IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OKLAHOMA

1. THE MUSCOGEE (CREEK) NATION,	
PLAINTIFF,	
v.	Case No. 18-cv-00180-JHP-JFJ
1. PURDUE PHARMA L.P.; **2. PURDUE PHARMA INC.;** **3. THE PURDUE FREDERICK COMPANY;** **4. ENDO HEALTH SOLUTIONS INC.; and** **5. ENDO PHARMACEUTICALS INC.;** **6. MCKESSON CORPORATION;** **7. CARDINAL HEALTH, INC.;** **8. AMERISOURCEBERGEN CORPORATION;** **9. CVS HEALTH CORPORATION;** **10. WALGREENS BOOTS ALLIANCE, INC.; and** **11. WAL-MART STORES, INC.**	**JURY TRIAL DEMANDED**
DEFENDANTS.	

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Plaintiff, the Muscogee (Creek) Nation ("Plaintiff" or "Nation"), brings this Complaint for compensatory, punitive, and other damages, and restitution, disgorgement, and civil penalties. The Defendants are (A) Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company, Endo Health Solutions Inc., and Endo Pharmaceuticals Inc. (collectively, "Manufacturer Defendants"); (B) McKesson Corporation, Cardinal Health, Inc., and AmerisourceBergen Corporation (collectively, "Distributor Defendants"); and (C) CVS Health Corporation, Walgreens Boots Alliance, Inc., and Wal-Mart Stores, Inc. (collectively, "Pharmacy Defendants").

INTRODUCTION

1. Prescription opioids are powerful pain-reducing medications. When used properly, they can help manage pain for certain patients. But, even then, these drugs can cause addiction, overdose, and death. When used to treat chronic pain, or when used for non-medical purposes, those risks are amplified.

2. In recent years, opioid use for both chronic pain and non-medical purposes has grown dramatically, resulting in an epidemic of abuse. Nationwide, millions of Americans are addicted to prescription opioids, and tens of thousands die annually from opioid overdoses. According to the Centers for Disease Control and Prevention ("CDC"), in Oklahoma, where the Nation is located, 2,315 people died of drug overdoses between 2014 and 2016, and the "main driver" of these deaths was prescription and illicit opioids.[1]

3. Defendants' conduct caused this epidemic.

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[1] CDC, *Drug Overdose Death Data*, https://www.cdc.gov/drugoverdose/data/statedeaths.html (last updated December 19, 2017) (777 deaths in 2014; 725 deaths in 2015; 813 deaths in 2016).

4. Manufacturer Defendants have engaged, and continue to engage, in a massive marketing campaign to misstate and conceal the risks of treating chronic pain with opioids. Although manufacturers are prohibited from marketing opioids through misstatements or omissions of material facts, Manufacturer Defendants did so through this campaign, which includes websites, promotional materials, conferences, guidelines for doctors, and other vehicles.

5. This aggressive marketing campaign enabled Manufacturer Defendants to overcome the longstanding medical consensus that opioids were unsafe for the treatment of chronic pain, and between 1999 and 2016, the number of opioids prescribed nationwide quadrupled,[2] as did deaths from prescription opioids.[3]

6. The increase in opioid prescriptions to treat chronic pain in turn led to a massive increase in the number of people seeking prescription opioids for non-medical uses and becoming addicted. Nationally, the number of people who take prescription opioids for non-medical purposes is now greater than the number of people who use cocaine, heroin, hallucinogens, and inhalants combined.[4] In Oklahoma alone, data from the Substance Abuse and

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[2] Li Hui Chen et al., *Drug-Poisoning Deaths Involving Opioid Analgesics: United States, 1999–2011*, 166 Nat'l Ctr. for Health Statistics Data Brief (Sept. 2014), https://www.cdc.gov/nchs/data/databriefs/db166.pdf; Rose A. Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015*, 65 Morbidity and Mortality Weekly Report 1445 (Dec. 30, 2016), https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm.

[3] Anna Lembke, *Drug Dealer MD: How Doctors Were Duped, Patients Got Hooked, and Why It's Hard to Stop* 4 (2016).

[4] Substance Abuse and Mental Health Servs. Admin., *Results from the 2009 National Survey on Drug Use and Health: Volume I. Summary of National Findings*, NSDUH Series H-38A, HHS Publication No. SMA 10-4586 Findings (2010).

Mental Health Services Administration indicate that over 194,000 residents use prescription opioids for non-medical purposes.[5]

7. Oklahoma, where the vast majority of Nation citizens reside, leads the country in opioid abuse. In recent years, it has ranked number one nationally for the non-medical use of prescription opioids for adults, and it currently ranks number five for drug overdose deaths. From 2007 to 2012, more overdose deaths in Oklahoma involved hydrocodone or oxycodone than alcohol, cocaine, methamphetamine, heroin, and all other illegal drugs combined. On information and belief, deaths of Nation citizens contribute to these statewide statistics, and Nation has suffered injury different in kind than the general public.

8. This increase in non-medical demand and addiction has led to an increase in diversion, which occurs when the supply chain of prescription opioids is broken and drugs are transferred from a legitimate channel to an illegitimate one.

9. The legitimate supply chain for prescription opioids begins with the manufacture and packaging of the pills. Manufacturers then transfer the pills to distributors—in particular Distributor Defendants, who, upon information and belief, together account for at least 85% of opioid shipments in the United States. Distributors (including Distributor Defendants) then supply opioids to pharmacies (including Pharmacy Defendants) and others who dispense the drugs to consumers.

10. At the distributor level, diversion occurs whenever opioid distributors fill suspicious orders from retailers such as pharmacies. As discussed below, under applicable state

[5] Substance Abuse and Mental Health Servs. Admin., *National Survey on Drug Use and Health: Comparison of 2002–2003 and 2013–2014 Population Percentages (50 States and the District of Columbia)* 16–17 (2015), http://www.samhsa.gov/data/sites/default/files/NSDUHsaeLongTermCHG2014/NSDUHsaeLongTermCHG2014.pdf.

law, suspicious orders include orders of an unusually large size, orders of a size that are disproportionately large in comparison to the population of a community served by a pharmacy, orders that deviate from a normal pattern, and orders of unusual frequency. Diversion also occurs when distributors allow opioids to be lost or stolen from inventory or in transit.

11. At the pharmacy level, diversion occurs when a pharmacist fills a prescription despite having reason to believe it has no legitimate medical purpose. A prescription may lack such a purpose when a patient is a drug dealer or opioid-dependent, seeks to fill multiple prescriptions from different doctors, travels great distances between a doctor and a pharmacy to fill a prescription, presents multiple prescriptions for the largest dose of more than one controlled substance such as opioids and benzodiazepines, or when there are other "red flags." Opioids are also diverted from pharmacies when they are stolen by employees or others, obtained with stolen or forged prescriptions, or sold without prescriptions.

12. Of the opioid prescriptions issued in Oklahoma each year, national studies suggest that as many as 12.8% of those prescriptions are diverted to non-medical uses.[6] These conclusions about the extent of opioid diversion are further supported by Drug Enforcement Administration ("DEA") data showing that in the past few years Oklahoma, where the Nation is

[6] The studies estimate that the percentage of prescription opioids that are diverted to illegitimate purposes ranges from 1.9% to 12.8% of total prescriptions. B.L. Wilsey et al., *Profiling Multiple Provider Prescribing of Opioids, Benzodiazepines, Stimulants, and Anorectics*, 112 Drug and Alcohol Dependence 99 (2010) (estimating that 12.8% of prescriptions are diverted); N. Katz et al., *Usefulness of Prescription Monitoring Programs for Surveillance–Analysis of Schedule II Opioid Prescription Data in Massachusetts, 1996–2006*, 19 Pharmacoepidemioloy and Drug Safety 115 (2010) (estimating the diversion rate at 7.7% when defining likely diversion as patients that obtain opioids from at least three prescribers and at least three pharmacies in a year); D.C. McDonald & K.E. Carlson, *Estimating the Prevalence of Opioid Diversion by "Doctor Shoppers" in the United States*, 8 PLoS ONE (2013) (estimating the diversion rate at 1.9% of all prescriptions and 4% of total grams dispensed).

located, has seen annual distribution exceeding 660 milligrams per citizen,[7] and 5,923 milligrams per opioid user.[8]

13. As detailed below, Distributor Defendants and Pharmacy Defendants have legal obligations to combat diversion. Distributor Defendants and Pharmacy Defendants have routinely and continuously violated these obligations, and instead have taken advantage of the massively increased demand for prescription opioids for non-medical uses by profiting heavily from the sale of opioids that they knew, or should have known, were being diverted from the legitimate supply chain to illegitimate channels of distribution. The failure of Distributor Defendants and Pharmacy Defendants to comply with their legal obligations to prevent diversion and to alert authorities to potential diversion continues today, despite (a) the well-known harm resulting from the opioid crisis, and (b) substantial fines for diversion levied against multiple Distributor Defendants and Pharmacy Defendants.

14. The misconduct of Defendants, including their consistent failure to comply with their legal obligations, has led to an epidemic of prescription opioid abuse. American Indians, including the Nation, have been significantly impacted by this epidemic. American Indians suffer the highest per capita rate of opioid overdoses.[9]

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[7] Drug Enf't Admin., ARCOS 3 – Report 1, *Retail Drug Distribution By Zip Code Within State by Grams Weight*,
https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/2013/2013_rpt1.pdf;
https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/2014/2014_rpt1.pdf;
https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/2015/2015_rpt1.pdf;
https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/report_yr_2016.pdf.

[8] Wenjun Zhong et al., *Age and Sex Patterns of Drug Prescribing in a Defined American Population*, 7 Mayo Clinic Proceedings 697, 700 (2013).

[9] National Congress of American Indians Policy Research Center, *Reflecting on a Crisis Curbing Opioid Abuse in Communities* (Oct. 2016), http://www.ncai.org/policy-research-center/research-data/prc-publications/Opioid_Brief.pdf.

15. Hundreds of American Indians have died of opioid overdoses in recent years. And for every opioid overdose death, there are 10 treatment admissions for abuse, 32 emergency room visits, 130 people who are addicted to opioids, and 825 non-medical users of opioids.[10]

16. The impact on American Indian children is particularly devastating. The CDC has reported that approximately one out of every 14.5 American Indian youths aged 12 or older used prescription opioids for non-medical purposes in 2012. This is 60% higher than the rate for white youths. Similarly, it has been reported that by twelfth grade, nearly 13% of American Indian teens have used OxyContin, an opioid manufactured by Defendant Purdue.[11] The fact that American Indian teens are easily able to obtain OxyContin at these alarming rates indicates the degree to which drug diversion has created an illegal secondary market for opioids.

17. The opioid epidemic resulting from Defendants' conduct has injured even the youngest members of Indian tribes. In 1992, in the United States, only 2% of pregnant women admitted for drug treatment services abused opioids. By 2012, opioids accounted for 38% of all drug treatment admissions.[12] Many tribal women have become addicted to prescription opioids and have used these drugs during their pregnancies. As a result, many tribal infants suffer from

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[10] Jennifer DuPuis, *The Opioid Crisis in Indian Country*, at 37, https://www.nihb.org/docs/06162016/Opioid%20Crisis%20Part%20in%20Indian%20Country.pdf (last visited Feb. 5, 2018); Gery P. Guy, Jr. et al., *Emergency Department Visits Involving Opioid Overdoses, U.S., 2010-2014*, 54 Am. J. of Preventive Medicine (Jan. 2018), http://www.ajpmonline.org/article/S0749-3797(17)30494-4/fulltext.

[11] Linda R. Stanley, *Rates of Substance Use of American Indian Students in 8th, 10th, and 12th Grades Living on or Near Reservations: Update, 2009–2012*, Pub. Health Rep. (Mar.–Apr. 2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3904895/table/T1/.

[12] Naana Afua Jumah, *Rural, Pregnant, and Opioid Dependent: A Systematic Review*, 10 Substance Abuse 35 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4915786/.

opioid withdrawal and Neonatal Abstinence Syndrome, which can have adverse short- and long-term developmental consequences.[13]

18. Pregnant American Indian women are up to 8.7 times more likely than others to be diagnosed with opioid dependency or abuse, and in some communities more than one in 10 pregnant American Indian women have a diagnosis of opioid dependency or abuse.[14] On information and belief, Nation women suffer from opioid dependency or abuse.

19. Defendants' opioid diversion on and around the Nation contributes to a range of social problems. Adverse impacts on the Nation's families include child abuse and neglect and family dysfunction. Nation children are regularly removed from their families as a result of prescription opioid dependency and abuse by both children and parents. These removals harm Nation children and families, and they harm the Nation itself, particularly when children are placed with families outside the Nation.

20. Other social problems caused by the opioid epidemic include criminal behavior, poverty, property damage, unemployment, and social despair. As a result of these adverse social outcomes, more and more Nation resources are devoted to addiction-related problems, leaving a diminished pool of resources available for education, cultural preservation, and social programs. Meanwhile, the prescription opioid crisis diminishes the Nation's available workforce, decreases productivity, increases poverty, and consequently requires greater expenditures for governmental assistance.

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[13] Jean Y. Ko et al., *CDC Grand Rounds: Public Health Strategies to Prevent Neonatal Abstinence Syndrome*, 66 Morbidity and Mortality Weekly Report 242 (Mar. 10, 2017), https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6609a2.pdf.
[14] DuPuis, *supra* note 9, at 64.

21. Damages suffered by the Nation include the costs of (a) medical care, therapeutic and prescription drugs, and other treatments for patients suffering from opioid-related addiction, overdoses, or disease; (b) law enforcement and public safety measures necessitated by the opioid crisis; (c) opioid-related counseling and rehabilitation services; (d) welfare for children whose parents suffer from opioid-related disease or incapacitation; (e) increased crime, property damage, and public blight caused by opioids; and (f) lost productivity of its citizens and businesses.

22. To remedy Defendants' misconduct, Plaintiff brings this action for: (a) violations of the Lanham Act; (b) common law nuisance; (c) negligence; (d) unjust enrichment; and (e) civil conspiracy.

23. Plaintiff seeks: (a) injunctive relief; (b) compensatory damages for the increased costs to the Nation's healthcare, criminal justice, social services, welfare, and education systems, as well as the cost of lost productivity; (c) statutory damages and penalties pursuant to Federal and applicable state law; (d) reimbursement of all payments fraudulently induced by Defendants' conduct; (e) disgorgement of all amounts unjustly obtained by Defendants; (f) restitution of all expenditures by the Nation resulting from Defendants' conduct; (g) punitive damages; (h) attorneys' fees and costs; and (i) such further relief as justice may require.

PARTIES

I. PLAINTIFF

24. The Nation is a federally recognized Indian tribe with a membership of 83,570 citizens. It covers 4,867 square miles that lie within the state of Oklahoma. It exercises sovereign governmental authority within its territory and over its citizens.

25. The Nation provides health care to its members and other Native Americans in the region pursuant to a compact under the Indian Self Determination and Education Assistance Act.[15]

26. Kevin Dellinger, Attorney General of the Nation, brings this action on behalf of the Nation in its proprietary capacity and under its *parens patriae* authority in the public interest to protect the health, safety, and welfare of the citizens of the Nation to stop the prescription opioid epidemic within the Nation and to recover damages and seek other redress from harm caused by Defendants' improper marketing, sales, distribution, dispensing, and reporting practices related to prescription opioids.

II. DEFENDANTS

A. Manufacturer Defendants

27. Defendant Purdue Pharma L.P. (together with Purdue Pharma Inc. and The Purdue Frederick Company, "Purdue") is a Delaware limited partnership with its principal place of business in Connecticut. During all relevant times, Purdue Pharma L.P. has manufactured and distributed substantial amounts of prescription opioids that have been and continue to be sold nationwide, including within Oklahoma and the Nation.

28. Defendant Purdue Pharma Inc. (together with Purdue Pharma L.P. and The Purdue Frederick Company, "Purdue") is a New York corporation with its principal place of business in Connecticut. During all relevant times, Purdue Pharma Inc. has manufactured and distributed substantial amounts of prescription opioids that have been and continue to be sold nationwide, including within Oklahoma and the Nation.

[15] 25 U.S.C. §§ 5301–5423.

29. Defendant The Purdue Frederick Company (together with Purdue Pharma L.P. and Purdue Pharma Inc., "Purdue") is a Delaware corporation with its principal place of business in Connecticut. At all relevant times, The Purdue Frederick Company has manufactured and distributed substantial amounts of prescription opioids that have been and continue to be sold in Oklahoma and the Nation.

30. Defendant Endo Health Solutions Inc. (together with Endo Pharmaceuticals Inc., "Endo") is a Delaware corporation with its principal place of business in Pennsylvania. At all relevant times, Endo Health Solutions Inc. has manufactured and distributed substantial amounts of prescription opioids that have been and continue to be sold within Oklahoma and the Nation.

31. Defendant Endo Pharmaceuticals Inc. (together with Endo Health Solutions Inc., "Endo") is a Delaware corporation with its principal place of business in Pennsylvania. At all relevant times, Endo Pharmaceuticals Inc. has manufactured and distributed substantial amounts of prescription opioids that have been and continue to be sold in Oklahoma and the Nation.

32. As discussed further below, in violation of their legal obligations, each Manufacturer Defendant has made misstatements or omitted information regarding the risks of using prescription opioids to treat chronic pain.

B. Distributor Defendants

33. Defendant McKesson Corporation ("McKesson") is a Delaware corporation with its principal place of business in California. McKesson is authorized to conduct business in Oklahoma. At all relevant times, McKesson has distributed substantial amounts of prescription opioids in Oklahoma and the Nation.

34. Defendant Cardinal Health, Inc. ("Cardinal") is an Ohio corporation with its principal place of business in Ohio. Cardinal is authorized to conduct business in Oklahoma. At

all relevant times, Cardinal has distributed substantial amounts of prescription opioids in Oklahoma and the Nation.

35. Defendant AmerisourceBergen Corporation ("AmerisourceBergen") is a Delaware corporation with its principal place of business in Pennsylvania. AmerisourceBergen is authorized to conduct business in Oklahoma. During all relevant times, AmerisourceBergen has distributed substantial amounts of prescription opioids in Oklahoma and the Nation.

36. As discussed below, each Distributor Defendant has consistently failed to comply with its legal obligations concerning opioid diversion, and has paid civil penalties to resolve government allegations regarding opioid diversion.

C. Pharmacy Defendants

37. Defendant CVS Health Corporation ("CVS") is a Delaware corporation with its principal place of business in Rhode Island. CVS is authorized to conduct business in Oklahoma. At all relevant times, CVS has sold and continues to sell prescription opioids at locations in Oklahoma that serve Nation citizens, including in close proximity to Nation hospitals, clinics, and other healthcare facilities serving patients of the Nation healthcare system.

38. Defendant Walgreens Boots Alliance, Inc., f/k/a Walgreen Co. ("Walgreens") is a Delaware corporation with its principal place of business in Illinois. Walgreens is authorized to conduct business in Oklahoma. At all relevant times, Walgreens has sold and continues to sell prescription opioids at locations in Oklahoma that service Nation citizens, including in close proximity to Nation hospitals, clinics, and other healthcare facilities serving patients of the Nation healthcare system.

39. Defendant Wal-Mart Stores, Inc. ("Walmart") is a Delaware corporation with its principal place of business in Arkansas. At all relevant times, Walmart has sold and continues to

sell prescription opioids at locations in Oklahoma that service Nation citizens, including in close proximity to Nation hospitals, clinics, and other healthcare facilities serving patients of the Nation healthcare system.

40. As discussed below, each Pharmacy Defendant has consistently failed to comply with its legal obligations concerning opioid diversion, and has paid civil penalties to resolve government allegations regarding opioid diversion.

JURISDICTION AND VENUE

41. This Court has subject-matter jurisdiction under 28 U.S.C. § 1331 because this action presents a federal question and under 28 U.S.C. § 1362 because this action is brought by an Indian tribe. This Court has supplemental jurisdiction over the state-law causes of action under 28 U.S.C. § 1367 because the state-law claims are part of the same case or controversy.

42. This Court has personal jurisdiction over all Defendants because each Defendant has substantial contacts and business relationships with Oklahoma, including consenting to be sued in Oklahoma by registering an agent for service of process and/or obtaining a distributor license, and has purposefully availed itself of business opportunities in Oklahoma, including by marketing, distributing, or selling prescription opioids in Oklahoma and within and around the Nation's communities.

43. Venue is proper in this Court under 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to this action occurred in this judicial district and because all Defendants are subject to this Court's jurisdiction.

FACTUAL BACKGROUND

I. PRESCRIPTION OPIOIDS ARE HIGHLY DANGEROUS

44. Prescription opioids are powerful pain-reducing medications that include non-synthetic, partially-synthetic, and fully-synthetic derivatives of the opium poppy. While these drugs can have benefits when used properly, they also pose serious risks. In particular, they present "substantially increase[d]" risk when used to treat chronic pain and "can cause serious harm, including addiction, overdose and death" when "misused or abused."[16]

45. Given these risks, the marketing, distribution, and sale of prescription opioids are heavily regulated by Federal law, including the Federal Controlled Substances Act, 21 U.S.C. §§ 801 *et seq.*, and the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S. §§ 321 *et seq.* Similarly, numerous state regulations, including numerous professional regulations related to persons who handle, prescribe, and dispense controlled substances, impose strict controls and requirements throughout the prescription opioid distribution chain.

46. As discussed below, despite the dangers of prescription opioids, Manufacturer Defendants wrongfully marketed them through misleading statements that minimized the risks of these drugs and failed to disclose accurately the true magnitude of those risks. The actions of Manufacturer Defendants created a huge market for prescription opioids, which in turn led to massive diversion of these drugs from legitimate to illegitimate channels. Distributor Defendants and Pharmacy Defendants, who have duties to prevent diversion, wrongfully turned a blind eye to it. As a result of the Defendants' wrongful acts, the Nation and its citizens have suffered injuries and damages.

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[16] Food and Drug Admin., *Opioid Medications*, https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm (last updated Feb. 15, 2018).

II. MANUFACTURER DEFENDANTS HAVE LEGAL DUTIES TO DISCLOSE ACCURATELY THE RISKS OF OPIOIDS

47. Each Manufacturer Defendant has a duty under Federal and Oklahoma law to exercise reasonable care in marketing and selling opioids.

48. The FDCA prohibits "the introduction . . . into interstate commerce of any . . . drug . . . that is adulterated or misbranded." 21 U.S.C. § 331(a). "Misbranding" includes misleading advertising. 21 U.S.C. § 352. Misleading advertising, in turn, includes both "representations made or suggested by statement, word, design, device, or any combination thereof," and

> the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

21 U.S.C. § 331(n).

49. Manufacturer Defendants also have a common law duty to make a full and fair disclosure as to the matters about which they choose to speak.

III. MANUFACTURER DEFENDANTS VIOLATED THEIR DUTIES

A. Manufacturer Defendants Made Misleading Statements About the Risks of Prescribing Opioids to Treat Chronic Pain and Failed to State Accurately the Magnitude of Those Risks

50. Manufacturer Defendants have engaged in a multi-million dollar marketing campaign to minimize and misstate the risks of addiction and abuse when prescription opioids are used to treat chronic pain.

51. Manufacturer Defendants made statements through websites, promotional materials, conferences, guidelines for doctors, and other vehicles that suggested that the risk of addiction when opioids are used for chronic pain was low—statements directly contrary to

established scientific evidence. Manufacturer Defendants' marketing claims also differ from the safety warnings that Manufacturer Defendants must place on many of their opioid products. In fact, as discussed further below, Manufacturer Defendants have been repeatedly fined or otherwise sanctioned for their misleading statements in the marketing of opioids.

1. Manufacturer Defendants Misrepresented the Risks of Addiction to Prescription Opioids

52. Manufacturer Defendants contributed content and funding to numerous "guidelines" on opioid use that misleadingly downplayed the risks of addiction when opioids are prescribed for chronic pain. For instance, "A Policymaker's Guide to Understanding Pain & Its Management," an October 2011 American Pain Foundation pamphlet "made possible by support from Purdue Pharma LP," asserted that "[l]ess than 1 percent of children treated with opioids become addicted" and that pain was generally "undertreated" due to "misconceptions about opioid addiction."[17] Similarly, "Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain," a February 2009 article funded by the American Pain Society and written by several authors with financial ties to Manufacturer Defendants, promoted opioids as "safe and effective" for chronic pain treatment and indicated that the risk of addiction was manageable for all patients regardless of past drug abuse history.[18] Likewise, "Treatment Options: A Guide for People Living with Pain," a 2006 American Pain Foundation pamphlet financially supported by Purdue, claimed that addiction is rare and limited to certain extreme

[17] Am. Pain Found., *A Policymaker's Guide to Understanding Pain & Its Management* (Oct. 2011), http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.
[18] Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, 10 The J. of Pain 113 (Feb. 2009), http://dx.doi.org/10.1016/j.jpain.2008.10.008.

cases.[19] Endo also sponsored the American Pain Foundation; in 2010 alone, the organization received more than $2,500,000 from Endo.[20]

53. Manufacturer Defendants produced and provided directly to doctors and patients marketing materials that made similar misstatements. Purdue issued marketing materials, starting in 1996, stating that "addiction to opioids legitimately used in the management of pain is very rare."[21] On information and belief, Endo distributed a pamphlet, "Living with Someone with Chronic Pain," which stated that most health care providers agree that most people do not develop an addiction.

54. Manufacturer Defendants ran websites that promoted similar misleading claims. For example, Endo sponsored painknowledge.com and painaction.com, which claimed, as of 2004 and 2015, respectively, that "[p]eople who take opioids as prescribed usually do not become addicted" and that "[m]ost chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

55. Endo also represented that "[t]aking opioids for pain relief is not addiction" and that "[a]ddiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don't need it for pain, maybe just to escape from your problem."[22] In the same publication, Endo suggested that patients use the following test to determine whether they are addicted to opioids: "Ask yourself: Would I want to take this medicine if my pain went

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[19] Am. Pain Found., *Treatment Options: A Guide for People Living with Pain* (2006), https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.
[20] Am. Pain Found., *2010 Annual Report* (Dec. 20, 2011), https://archive.org/details/277604-apf-2010-annual-report.
[21] Drug Label for Oxycodone Hydrochloride 5mg Capsule, https://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=41068.
[22] Endo Pharmaceuticals, *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004), https://perma.cc/QN86-62PK.

away? If you answer no, you are taking opioids for the right reasons—to relieve pain and improve your function. You are not addicted."[23]

56. Manufacturer Defendants trained salesmen to minimize the risk of addiction. For instance, Purdue salesmen were instructed to tell doctors that opioids' addiction risk was "less than one percent."[24]

57. Manufacturer Defendants sponsored training sessions where doctors were given similar misleading information regarding the risks of opioid addiction. For example, Purdue sponsored training sessions in the late 1990s and early 2000s where opioid addiction was described as "exquisitely rare."[25]

58. All these statements were false. The CDC has stated that: (1) there is "extensive evidence" of the possible harms of opioids, including addiction; (2) "[o]pioid pain medication use presents serious risks," including addiction; and (3) using opioids to treat chronic pain "substantially increases" the risk of addiction.[26] Studies have found that up to 26% of long-term users of opioids experience problems with addiction or dependence.[27]

59. Moreover, in August 2016, the U.S. Surgeon General expressed concern that "heavy marketing to doctors" had led many to be "taught – incorrectly – that opioids are not

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[23] *Id.*
[24] U.S. Gov't Accountability Office, *Prescription Drugs: OxyContin abuse and diversion and efforts to address the problem* (Dec. 2003), https://www.gpo.gov/fdsys/pkg/GAOREPORTS-GAO-04-110/content-detail.html.
[25] Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* 190 (2003).
[26] Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65 Morbidity and Mortality Weekly Report 1 (2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.
[27] *Id.*

addictive when prescribed for legitimate pain," and noted the "devastating" results that followed from this misinformation.[28]

60. Findings by the Food and Drug Administration ("FDA") similarly belie Manufacturer Defendants' assertions that opioids are safe for treating chronic pain. These findings show that: (1) "most opioid drugs have 'high potential for abuse'"; (2) treatment of chronic pain with opioids poses "known serious risks," including "addiction, abuse, and misuse . . . overdose and death" even when used "at recommended doses"; and (3) opioids should be used only "in patients for whom alternative treatment options" have failed.[29] And several studies finding double-digit rates of prescription drug abuse in chronic pain patients controvert Manufacturer Defendants' claims that addiction rates are only one percent.[30]

61. Similarly, a prominent neuropharmacologist at the Washington University School of Medicine in St. Louis, Dr. Theodore Cicero, remarked in 2016 that Purdue's OxyContin dosing is "the perfect recipe for addiction" due to its encouragement of psychological and physical withdrawal symptoms.[31]

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[28] Letter from U.S. Surgeon General Vivek H. Murthy (Aug. 2016), https://perma.cc/VW95-CUYC.

[29] Letter from Janet Woodcock, M.D., Dir. of Food and Drug Admin., Center for Drug Evaluation and Research, to Andrew Kolodny, M.D. Responding to Petition Submitted by Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), http://www.supportprop.org/wp-content/uploads/2014/12/FDA_CDER_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf.

[30] Caleb J. Banta-Green et al., *Opioid Use Behaviors, Mental Health and Pain—Development of a Typology of Chronic Pain Patients*, 104 Drug and Alcohol Dependence 34 (Sept. 2009), http://dx.doi.org/10.1016/j.drugalcdep.2009.03.021; Joseph A. Boscarino et al., *Risk Factors for Drug Dependence Among Out-Patients on Opioid Therapy in a Large US Health-Care System*, 105 Addiction 1776 (Oct. 2010), http://dx.doi.org/10.1111/j.1360-0443.2010.03052.x; Jette Højsted et al., *Classification and Identification of Opioid Addiction in Chronic Pain Patients*, 14 European J. of Pain 1014 (Nov. 2010), http://dx.doi.org/10.1016/j.ejpain.2010.04.006.

[31] Harriet Ryan et al., '*You Want a Description of Hell?*' *OxyContin's 12-Hour Problem*, L.A. Times (May 5, 2016), http://www.latimes.com/projects/oxycontin-part1/.

62. As recently as June 2017, the New England Journal of Medicine published an analysis finding that Purdue's introduction of OxyContin into the marketplace coincided with a significant increase in misleading dissemination of the claim that addiction to opioids is rare. Moreover, this analysis concluded that "[w]e believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy."[32]

2. Manufacturer Defendants Misleadingly Claimed that Patients Who Were Showing Signs of Addiction Were Not Actually Addicted

63. Manufacturer Defendants also made false statements that individuals showing signs of opioid addiction might instead have untreated pain requiring additional opioids—a baseless theory labeled "pseudoaddiction."

64. On information and belief, Purdue published a physician education pamphlet in 2011 suggesting that drug-seeking behavior could be a sign of "pseudoaddiction," which was described as "[drug-seeking behaviors] in patients who have pain that has not been effectively treated." Purdue used the term "pseudoaddiction" in numerous other marketing materials, including one entitled "Responsible Opioid Prescribing – A Physician's Guide."[33] On information and belief, Endo also published materials promoting "pseudoaddiction."

65. However, there is no scientific support for the concept of "pseudoaddiction," a term coined by Dr. J. David Haddox, the Vice President of Health Policy for Purdue.[34] In fact,

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[32] Pamela T. M. Leung et al., *A 1980 Letter on the Risk of Opioid Addiction*, 376 New England J. of Med. 2194 (June 1, 2017), http://www.dx.doi.org/10.1056/NEJMc1700150.
[33] Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide* (2007).
[34] Marion S. Greene & R. Andrew Chambers, *Pseudoaddiction: Fact or fiction? An Investigation of the Medical Literature*, 2 Current Addiction Reports 310 (Oct. 1, 2015), http://dx.doi.org/10.1007/s40429-015-0074-7.

Endo's Vice President for Pharmacovigilance and Risk Management recently testified that he was not aware of any research validating the "'pseudoaddiction' concept."[35]

66. The 2016 CDC guideline rejects the notion of pseudoaddiction. Instead of recommending that opioid doses be increased if patients do not obtain relief, the guideline states that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer term use"[36] and that doctors should "reassess[] pain and function within 1 month" so as to "minimize risks of long-term opioid use . . . ."[37]

3. Manufacturer Defendants Falsely Claimed There Was No Risk in Increasing Opioid Dosages to Treat Chronic Pain

67. Manufacturer Defendants also falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk.

68. Guidelines edited and sponsored by Purdue and Endo[38]—namely "Treatment Options: A Guide for People Living with Pain" (2006) and "A Policymaker's Guide to Understanding Pain & Its Management" (2011)—claim that: (a) some patients "need" a larger opioid dose, regardless of the dose prescribed; (b) opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain; and (c) dosage escalations, even unlimited ones, are "sometimes necessary."[39]

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[35] Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15 at 7, *In re Endo Health Solutions Inc.*, No. 15-228 (Attorney General of the State of N.Y. 2016), https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

[36] Deborah Dowell, Tamara Haegerich, & Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65 Morbidity and Mortality Weekly Report 1, 13 (2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

[37] *Id.* at 25.

[38] Am. Pain Found., *2010 Annual Report* (Dec. 20, 2011), https://archive.org/details/277604-apf-2010-annual-report.

[39] Am. Pain Found., *Treatment Options: A Guide for People Living with Pain* (2006), https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf; Am. Pain Found.,

69. As recently as June 2015, Purdue's "In the Face of Pain" website was promoting the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, the patient should find another doctor who will. Also in 2015, Purdue presented a paper on the Problems of Drug Dependence, challenging the correlation between opioid dosage and overdose.[40] And in 2016, Purdue's Dr. Haddox falsely claimed that evidence does not show that Purdue's opioids are being abused in large numbers.[41]

70. Endo distributed a pamphlet in 2004, "Understanding Your Pain: Taking Oral Opioid Analgesics," which stated that patients "won't 'run out' of pain relief" so long as they increase dosages.[42] Endo also sponsored a website from 2004 to 2007, painknowledge.com, which claimed that opioid dosages may be increased until "you are on the right dose of medication for your pain."

71. Manufacturer Defendants made these statements despite strong contrary scientific evidence. The FDA has stated that the available data "suggest a relationship between increasing opioid dose and risk of certain adverse events."[43] The CDC has stated that there is "an

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A Policymaker's Guide to Understanding Pain & Its Management (Oct. 2011), http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

[40] A. DeVeaugh-Geiss et al., *Is Opioid Dose a Strong Predictor of the Risk of Opioid Overdose?: Important Confounding Factors That Change the Dose-Overdose Relationship*, CPDD 76th Annual Scientific Meeting Program (June 2014), http://cpdd.org/wp-content/uploads/2016/07/2014CPDDprogrambook.pdf.

[41] Harrison Jacobs, *There is a Big Problem with the Government's Plan to Stop the Drug-Overdose Epidemic*, Business Insider, Mar. 14, 2016, http://www.businessinsider.com/robert-califf-abuse-deterrent-drugs-have-a-big-flaw-2016-3.

[42] Endo Pharmaceuticals, *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004), https://perma.cc/QN86-62PK.

[43] Letter from Janet Woodcock, M.D., Dir. of Food and Drug Admin., Ctr. for Drug Evaluation and Research, to Andrew Kolodny, M.D. Responding to Petition Submitted by Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), http://www.supportprop.org/wp-content/uploads/2014/12/FDA_CDER_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf.

established body of scientific evidence showing that overdose risk is increased at higher opioid dosages," and has specifically recommended that doctors "avoid increasing doses" above 90 morphine milligram equivalents ("MME") per day. [44]

72. Nonetheless, Manufacturer Defendants misrepresented the effects of escalating dosages to further their relentless pursuit of corporate profit. The ability to escalate dosages was critical to Manufacturer Defendants' efforts to market opioids for chronic pain treatment because doctors would otherwise abandon treatment when patients built up tolerance and no longer obtained pain relief. And for at least some products, escalation of dosage was key: of the seven available OxyContin tablet strengths, the three strongest—40 milligrams (120 MME), 60 milligrams (180 MME), and 80 milligrams (240 MME)—all exceed the CDC limit when taken twice per day as directed.

B. Manufacturer Defendants' Misleading Statements Were Designed for Maximum Effect and Targeted to Specific Audiences

73. Manufacturer Defendants disseminated these misstatements to doctors through multiple sources, each designed to maximize impact and targeted to a specific receptive audience.

74. Manufacturer Defendants often delivered their misstatements through "opinion leaders"—doctors in the field of pain management who were heavily funded by Manufacturer Defendants. Manufacturer Defendants frequently used opinion leaders to deliver their message because they knew that doctors often place great confidence in seemingly independent peers.

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[44] Deborah Dowell, Tamara Haegerich, & Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65 Morbidity and Mortality Weekly Report 1 (2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

75. One notable opinion leader was Dr. Russell Portenoy, who held himself out as an unbiased expert on opioids but received substantial funding from Manufacturer Defendants. Dr. Portenoy gave, in his words, "innumerable" lectures and media appearances promoting opioids.[45] During these appearances, he routinely downplayed the dangers of opioids. In 2010, he said on Good Morning America that "[a]ddiction, when treating pain, is distinctly uncommon" and that "most doctors can feel very assured that that person is not going to become addicted." He also regularly repeated—including in a 1986 paper published in the journal of the American Pain Society, a 1996 paper written on behalf of the American Pain Society and the American Academy of Pain, and numerous lectures—the unsubstantiated claim that the addiction risk posed by opioids was lower than one percent.[46] Dr. Portenoy later conceded that some of his statements were misleading. In December 2012, he was quoted as saying, "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."[47]

76. Between 2001 and 2010, Purdue's "In the Face of Pain" website similarly presented statements of Dr. Portenoy and other opinion leaders who were portrayed as independent experts. The website did not disclose that Purdue had paid many of these opinion

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[45] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal, Dec. 17, 2012, https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

[46] Russell Portenoy & K. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases*, 25 Pain 171 (May 1986), https://www.ncbi.nlm.nih.gov/pubmed/2873550; Russell Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: A Review of the Critical Issues*, 11 J. of Pain and Symptom Mgmt. 203 (Apr. 1996), http://dx.doi.org/10.1016/0885-3924(95)00187-5; Russell Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain*, 1 Pain Research and Mgmt. 17 (1996), http://downloads.hindawi.com/journals/prm/1996/409012.pdf.

[47] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal, Dec. 17, 2012, https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

leaders for other work, and did not identify Purdue's involvement beyond a small copyright notice at the bottom of the website.[48]

77. Manufacturer Defendants also often disseminated their misstatements through industry groups that presented themselves as independent patient advocacy organizations, but whose content and funding came largely from Manufacturer Defendants. These groups included the American Pain Foundation, the American Pain Society, and the American Academy of Pain Medicine. Much like the opinion leaders, these industry groups allowed Manufacturer Defendants to present their misstatements as if they came from unbiased experts.

78. These groups published many of the misleading "guidelines" described above, based on content and funding provided by Manufacturer Defendants, including: (1) "Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain" (2009);[49] (2) "A Policymaker's Guide to Understanding Pain & Its Management" (2011);[50] and (3) "Treatment Options: A Guide for People Living with Pain" (2006).[51] In 2007, the American Pain Society repeated Manufacturer Defendants' misstatements that addiction was a "rare problem" for patients using opioids for chronic pain and that there was "no causal effect . . . between the marketing of [a particular opioid] and the abuse and diversion of the drug."[52]

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[48] Advocacy Voices, In the Face of Pain (archived Nov. 7, 2010), https://web.archive.org/web/20101107090355/http://www.inthefaceofpain.com:80/search.aspx?cat=4#7.

[49] Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, 10 The J. of Pain 113 (Feb. 2009), http://dx.doi.org/10.1016/j.jpain.2008.10.008.

[50] Am. Pain Found., *A Policymaker's Guide to Understanding Pain & Its Management* (Oct. 2011), http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

[51] Am. Pain Found., *Treatment Options: A Guide for People Living with Pain* (2006), https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

[52] *Evaluating the Propriety and Adequacy of the OxyContin Criminal Settlement: Hearing Before the S. Comm. on Judiciary*, 110th Cong. 1 (2007) (Statement of James Campbell, M.D.).

79. Manufacturer Defendants also conducted conferences, training sessions, and educational programs for doctors, often with all expenses paid at resort destinations. These events were useful to Manufacturer Defendants because studies show that such events influence the attending practitioners' prescribing habits and views towards a drug.[53]

80. From 1996 to 2001, Purdue conducted over 40 pain management and speaker training sessions at resorts to recruit and train physicians, nurses, and pharmacists as speakers on its behalf.[54] Purdue trained over 5,000 people at these all-expenses-paid events.[55] The DEA has estimated that Purdue funded over 20,000 opioid pain-related programs between 1996 and July 2002 through direct sponsorship or financial grants.[56]

81. Manufacturer Defendants also used direct salesmen to market opioids. These salesmen often received the majority of their compensation based on individual sales figures, ensuring that they were strongly motivated to present their audiences with misleading information minimizing the risks of opioids.[57]

82. In addition, Manufacturer Defendants targeted marketing to doctors who would be most receptive to the misstatements.

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[53] Ray Moynihan, *Doctors' Education: The Invisible Influence of Drug Company Sponsorship*, 336 The BMJ 416 (Feb. 21, 2008), http://dx.doi.org/10.1136/bmj.39496.430336.DB; A.C. Anand, *Professional Conferences, Unprofessional Conduct*, 67 Medical J. Armed Forces India 2 (Jan. 2011), http://dx.doi.org/10.1016/S0377-1237(11)80002-X; David McFadden et al., *The Devil Is in the Details: The Pharmaceutical Industry's Use of Gifts to Physicians as Marketing Strategy*, 140 J. of Surgical Research 1 (2007), http://dx.doi.org/10.1016/j.jss.2006.10.010.

[54] U.S. Gov't Accountability Office, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem* (Dec. 2003), https://www.gpo.gov/fdsys/pkg/GAOREPORTS-GAO-04-110/content-detail.html.

[55] *Id.*

[56] *Id.*

[57] *Id.*

83. Manufacturer Defendants specifically targeted their marketing to primary care physicians, who are generally less aware of the medical literature regarding the dangers of treating chronic pain with opioids. One longtime Purdue collaborator speaking to an FDA advisory panel on January 30, 2002 acknowledged that "[g]eneralists are adopting [opioid] therapy without adequate knowledge of pain management principles."[58] On information and belief, Manufacturer Defendants also targeted susceptible patients like veterans and the elderly.

84. Manufacturer Defendants developed methods to target doctors who were already prescribing higher-than-average numbers of opioids. Purdue created a database to identify doctors with large numbers of chronic-pain patients (which also showed which doctors most frequently prescribed opioids). This database gave Purdue extensive knowledge of where and how its drugs are being used, including in Oklahoma, and has allowed Purdue to target doctors already susceptible to its message.[59]

C. Manufacturer Defendants Knew or Should Have Known That Their Statements Were Misleading

85. The problems caused by the deceptive, unfair, and false marketing of opioids were specifically known by Manufacturer Defendants. Manufacturer Defendants knew their statements were misleading not only because they knew their statements were contrary to established fact, but also because they were fined and otherwise sanctioned by various government entities for misleading marketing.

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[58] Food and Drug Admin., Anesthetic and Life Support Drugs Advisory Comm., Tr. of Meeting (Jan. 30, 2002), https://www.fda.gov/ohrms/dockets/ac/02/transcripts/3820t1.pdf.

[59] Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 Am. J. of Public Health 221, 222 (Feb. 2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/pdf/221.pdf.

86. In 2007, Purdue settled federal allegations that it had introduced misbranded drugs into interstate commerce. Purdue paid over $700 million, and three of its former executive officers pleaded guilty to federal crimes.[60] Purdue acknowledged that "some employees made, or told other employees to make, certain statements about OxyContin to some healthcare professionals that were inconsistent with the FDA-approved prescribing information for OxyContin and the express warning it contained about risks associated with the medicine."[61]

87. In August 2015, New York State settled claims against Purdue related to its marketing and sales practices. The settlement required Purdue to ensure that its sales representatives flag doctors and other professionals who were improperly prescribing and/or diverting opioids, stop calling and/or marketing to doctors on the company's "no-call list," and inform health care providers about FDA-approved training programs regarding the appropriate prescription of opioids. The agreement also required Purdue to stop representing that its website "www.inthefaceofpain.com" was neutral or unbiased, and to disclose the financial relationship Purdue's purportedly neutral experts have with Purdue.[62]

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[60] Plea Agreement at 4, *United States v. The Purdue Frederick Co.*, No. 1:07-cr-00029-JPJ (W.D. Va. May 10, 2017).

[61] Shannon Henson, *Purdue, Employees to Pay $700M in OxyContin Case*, LAW360, (May 10, 2007, 12:00 AM), https://www.law360.com/illinois/articles/24509/purdue-employees-to-pay-700m-in-oxycontin-case.

[62] Press Release, N.Y. State Office of the Attorney General, A.G. Schneiderman Announces Settlement with Purdue Pharma That Ensures Responsible and Transparent Marketing of Prescription Opioid Drugs by the Manufacturer (August 20, 2015), https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-purdue-pharma-ensures-responsible-and-transparent.

88. In August 2017, Purdue settled, for over $20 million, claims by numerous Canadian plaintiffs that the company failed to warn about the dangers of OxyContin, including its addictive properties.[63]

89. In 2016, Endo settled claims with New York and agreed to halt misleading advertisements in New York about the safety of opioids. The State had found that opioid use disorders "appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder."[64] Endo had claimed on its website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but New York found that Endo had no evidence for that statement.[65] Consistent with this finding, Endo agreed not to make statements in New York that opioids "generally are non-addictive" or "that most patients who take opioids do not become addicted."[66]

90. Manufacturer Defendants have also represented to the public that they are taking steps to curb the opioid epidemic, rather than creating it.

a. As recently as November 2017, Purdue stated on its website that ". . . too often these medications [opioids] are diverted, misused, and abused. Teenagers, in particular, are

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[63] *See* Will Davidson LLP, *Purdue Pharma Agrees to OxyContin Settlement, but Is it Fair?*, Lexology (Aug. 22, 2017), https://www.lexology.com/library/detail.aspx?g=d53ee1ee-44cb-4ef5-b916-e570a385b568.

[64] Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15 at 7, *In re Endo Health Solutions Inc.*, No. 15-228 (Attorney General of the State of N.Y. 2016), https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

[65] *Id.*

[66] *Id.*

vulnerable to prescription drug abuse, which has become a national epidemic."[67] In response to the misuse of opioids, Purdue said that "Corporations have a responsibility to address this issue, and Purdue has dedicated vast resources for helping to prevent drug abuse . . . ."[68]

b. Purdue also stated in November 2017 that it is "committed to being part of the solution to prescription drug abuse" and that it "offers an array of programs focused on education, prevention, and deterrence, and through partnerships with (1) healthcare professionals, (2) families and communities, and (3) law enforcement and government" to combat the "widespread abuse of opioid prescription pain medications [that] can lead to tragic consequences, including addiction, overdose, and death."[69]

c. Also in November 2017, Purdue discussed the opioid epidemic and its response to it, stating that "The nation is experiencing a public health crisis involving licit and illicit opioids. Purdue endorses the following policies that support a comprehensive approach to reducing addiction, abuse, diversion, and overdose related to opioids."[70] Those policies include limiting the duration of one's first opioid prescription; use of prescription drug monitoring programs; requiring demonstrated competence for opioid prescribing; and expanding the use of naloxone, an opioid reversal agent.

91. However, on information and belief, these representations are untrue. For example, despite its public statements of corporate responsibility, and its "constructive role in the

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[67] Purdue Pharma, *Combating Opioid Abuse*, http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/combating-opioid-abuse/ (last visited Mar. 26, 2018).
[68] *Id.*
[69] Purdue Pharma, *Responsible Use of Opioids*, http://www.purduepharma.com/patients-caregivers/responsible-use-of-opioids/ (last visited Mar. 26, 2018).
[70] Purdue Pharma, *Public Policies to Address the Opioid Crisis*, http://www.purduepharma.com/about/purdue-pharma-public-policy/ (last visited Mar. 26, 2018).

fight against opioid abuse" and "strong record of coordination with law enforcement, Purdue has failed to report to authorities illicit or suspicious prescribing of its opioids."[71]

92. In 2012, Endo took the remarkable step of asserting that the FDA should block generic versions of Endo's Opana ER because the drug was dangerously susceptible to abuse and misuse.[72] Endo made no such assertions before it faced financial competition regarding the drug.

93. Additionally, since at least 2002, Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. According to Purdue, physicians could be added to this database based on observed indicators of illicit prescribing, such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing volume. Purdue has said publicly that "[o]ur procedures help ensure that whenever we observe potential abuse or diversion activity, we discontinue our company's interaction with the prescriber or pharmacist and initiate an investigation."[73]

94. Yet, according to a 2016 investigation by the Los Angeles Times, Purdue failed to cut off these providers' opioid supply at the pharmacy level and failed to report these providers to state medical boards or law enforcement —meaning Purdue continued to generate sales revenue from their prescriptions.[74]

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[71] *See* Press Release, Purdue Pharma L.P., Setting the Record Straight on OxyContin's FDA-Approved Label (May 5, 2016), http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontins-fda-approved-label/; Press Release, Purdue Pharma L.P., Setting the Record Straight on Our Anti-Diversion Programs (July 11, 2016), http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/.

[72] *See* David Heath, *Drugmaker Set to Profit from an Opioid it Said Was Unsafe*, CNN, Oct. 30, 2017, http://www.cnn.com/2017/10/30/health/opana-endo-opioid-profit/index.html.

[73] *Id.*

[74] *See* Harriet Ryan et al., *More Than 1 Million OxyContin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, L.A. Times, July 10, 2016, http://www.latimes.com/projects/la-me-oxycontin-part2/.

95. This investigation also found that for over a decade, Purdue "collected extensive evidence suggesting illegal trafficking of OxyContin" but consistently failed to report suspicious dispensing or stop supplies to pharmacies.[75] Despite knowing of illicit prescribing, Purdue did not report its suspicions until years after law enforcement shut down a Los Angeles clinic that Purdue's district manager described internally as "an organized drug ring" and that had prescribed over 1.1 million OxyContin tablets.[76]

D. Manufacturer Defendants' Conduct Violated Their Duties

96. Manufacturer Defendants have continued to promote, directly and indirectly, deceptive marketing messages that misrepresent, and fail to include material facts about, the dangers of opioid usage, despite actual or constructive knowledge that the opioids were ultimately being consumed for unsafe and non-medical purposes.

97. Manufacturer Defendants have negligently or recklessly failed to control adequately the content and distribution of marketing materials and sales efforts regarding opioids. A reasonably prudent manufacturer of opioids would have anticipated the dangers of widely advertising and distributing dangerous opioid products and protected against it. A reasonably prudent manufacturer could have (a) ensured physicians were judicious in considering when to prescribe opioids; (b) carefully worded its marketing materials to ensure the risks of opioids were clearly communicated; (c) conducted and publicized scientific studies testing the risks of opioid products; (d) taken greater care in hiring, training, and supervising employees responsible for marketing and selling opioid products; (e) investigated demographic or epidemiological data concerning the increasing demand for narcotic painkillers and the

[75] *Id.*
[76] *Id.*

linkage of that demand with Manufacturer Defendants' marketing efforts; and (f) followed applicable statutes, regulations, professional standards, and guidance, as Manufacturer Defendants agreed to do when settling prior actions against them.

98. On information and belief, Manufacturer Defendants failed to take any of these steps to prevent their misrepresentations and omissions from contributing to the opioid epidemic.

IV. DISTRIBUTOR DEFENDANTS AND PHARMACY DEFENDANTS HAVE LEGAL DUTIES TO PREVENT OPIOID DIVERSION

99. Each Distributor Defendant and each Pharmacy Defendant has a common law duty to exercise reasonable care under the circumstances. In addition, each Distributor Defendant and each Pharmacy Defendant assumes a duty, when it speaks publicly about opioids, to speak accurately.

100. Moreover, applicable state and Federal laws and regulations impose duties on Distributor Defendants and Pharmacy Defendants, and create a standard of conduct to which they must adhere.

101. These statutes and regulations were designed to prevent drug diversion (which, as discussed above, occurs whenever the supply chain of prescription opioids is broken and the drugs are transferred from a legitimate channel to an illegitimate one) by creating a legal framework for distributing and dispensing controlled substances and monitoring and controlling them from manufacture through delivery to the patient. These statutes and regulations include the Federal Controlled Substances Act ("FCSA"), 21 U.S.C. §§ 801 *et seq.*, state controlled substances acts, laws regarding branding of drugs, and regulations related to persons who handle, prescribe, and dispense controlled substances. These statutes and regulations impose strict controls throughout the prescription opioid distribution chain.

102. The Nation is not asserting a cause of action under these laws. But just as a driver's violation of a speed limit can demonstrate that he acted negligently, so, too, Distributor Defendants' and Pharmacy Defendants' violations of applicable state and Federal laws and regulations show that they failed to meet the relevant standard of care.

A. Federal Law Sets a Standard of Care for Distributor Defendants to Follow

103. On information and belief, each Distributor Defendant distributes opioids throughout the State of Oklahoma including within and around the Nation.

1. Duties Under Federal Laws and Regulations

104. The FCSA sets the standard of conduct to which Distributor Defendants must adhere. The FCSA requires all opioid distributors to maintain effective controls against opioid diversion and to employ a system to identify and report to law enforcement suspicious orders of controlled substances.

105. Distributor Defendants must (a) send transaction data to the DEA on each acquisition or reduction of inventory, as well as any lost or stolen inventory, and (b) maintain a complete and accurate record of each substance manufactured, sold, delivered, or otherwise disposed of. 21 U.S.C. § 827(a).

106. Importantly, Distributor Defendants must employ a system to inform the DEA of suspicious orders. 21 C.F.R. § 1301.74(b).

107. The DEA's Automation of Reports and Consolidation Orders System ("ARCOS") accumulates data on distributors' controlled substances transactions, which are then summarized into reports used by the DEA to identify any diversion of controlled substances into illicit channels of distribution. 21 C.F.R. § 1304.33.

B. Federal Law Sets a Standard of Care for Pharmacy Defendants to Follow

108. The FCSA also impose specific obligations on Pharmacy Defendants. These requirements, along with their related regulations and agency interpretations, set a standard of care for pharmacy conduct.

1. Duties Under Federal Laws and Regulations

109. The FCSA requires pharmacists to review each controlled substance prescription and, prior to dispensing medication, make a professional determination that the prescription is effective and valid.

110. Under the FCSA, pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances." *See* 21 C.F.R. § 1301.71(a). In addition, 21 C.F.R. § 1306.04(a) states, "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a *corresponding responsibility* rests with the pharmacist who fills the prescription." (Emphasis added.)

111. Therefore, pharmacists must ensure that prescriptions for controlled substances are valid, and that they are issued for a legitimate medical purpose by an individual practitioner who is approved and registered with the DEA to write prescriptions for opioids acting in the usual course of his professional practice.

112. The DEA has informed pharmacists that "[a]n order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is an invalid prescription."[77] Filling such a prescription is illegal. As the

[77] Michele Leonhart et al., *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act*, Drug Enf't Admin., Diversion Control Div. (Revised 2010), https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/.

DEA states, "The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin. To the contrary, the pharmacist who deliberately ignores a questionable prescription when there is reason to believe it was not issued for a legitimate medical purpose may be [criminally] prosecuted."[78]

113. Questionable or suspicious prescriptions include: (a) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities) for controlled substances than other practitioners in the area; (b) prescriptions which should last for a month in legitimate use, but are refilled more frequently; (c) simultaneous prescriptions for antagonistic drugs, such as depressants and stimulants; (d) prescriptions that look "too good" or where the prescriber's handwriting is too legible; (e) prescriptions with atypical quantities or dosages; (f) prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; (g) photocopied prescriptions; or (h) prescriptions containing different handwritings. Most of the time, these questionable or suspicious attributes are not difficult to detect or recognize; they should be apparent to an adequately trained pharmacist.

114. Pharmacists are also instructed to be suspicious of signs that a customer is seeking to divert opioids, including customers who: (a) appear to be returning too frequently; (b) are seeking to fill a prescription written for a different person; (c) appear at the pharmacy counter simultaneously, or within a short time, all bearing similar prescriptions from the same physician; (d) are not regular patrons or residents of the community, and present prescriptions from the same physician; (e) drive long distances to have prescriptions filled; (f) seek large volumes of controlled substances in the highest strength in each prescription; (g) seek a combination of other drugs with opioids such as tranquilizers and muscle relaxers that can be used to create an "opioid

[78] *Id.*

cocktail"; and (h) pay large amounts of cash for their prescriptions rather than using insurance. Ignoring these suspicious signs violates industry standards and DEA guidelines and is illegal under multiple laws.

115. Other "red flags" that should alert a pharmacist to potential diversion include: (a) prescriptions that lack the technical requirements of a valid prescription, such as a verifiable DEA number and signature; (b) prescriptions written in excess of the amount needed for proper therapeutic purposes; (c) prescriptions obtained through disreputable or illegal web-based pharmacies; and (d) patients receiving multiple types of narcotic painkillers on the same day.

116. Each prescriber of controlled substances is issued a number identification by the DEA and must sign each prescription. Industry standards require pharmacists to contact the prescriber for verification or clarification whenever there is a question about any aspect of a prescription. If a pharmacist believes the prescription is forged or altered, he or she should not fill it, but instead should call the local police. If a pharmacist believes there is a pattern of prescription abuse, the local Board of Pharmacy and the DEA must be contacted.

C. Oklahoma Law Sets a Standard of Care for Distributor Defendants to Follow

117. On information and belief, each Distributor Defendant distributes opioids throughout Oklahoma including within the exterior boundaries of the Nation.

1. Duties Under State Laws and Regulations

118. In addition to having common law duties and duties under Federal law, the Distributor Defendants are governed by the Oklahoma Uniform Controlled Dangerous Substances Act ("Oklahoma CSA"), 63 Okl. Stat. Chapter 2, and the duties imposed in the statute and its implementing regulations. The Distributor Defendants' violation of these

requirements shows that they failed to meet the relevant standard of conduct society expects from them.

119. The Oklahoma CSA creates a legal framework for the distribution and dispensing of opioids in Oklahoma. Defendants' violation of these laws constitutes negligence.

120. The Oklahoma CSA acts as a system of checks and balances from the manufacturing level through delivery of the pharmaceutical drug to the ultimate user. Every person or entity who manufactures, distributes, or dispenses opioids must obtain a "registration" from the Director of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control. Registrants at every level of the prescription opioid supply chain must fulfill their obligations under the Oklahoma CSA, otherwise there is great potential for harm to the Nation.

121. Under the Oklahoma CSA and the Oklahoma administrative code, distributors must maintain effective controls against opioid diversion. They must also create and use a system to identify and report suspicious orders of controlled substances to law enforcement. Suspicious orders include orders of unusual size, orders deviating substantially from the normal pattern, and orders of unusual frequency. To comply with these requirements, distributors must know their customers, report suspicious orders, conduct due diligence, and terminate orders that suggest diversion.

122. To prevent unauthorized users from obtaining opioids, Oklahoma law creates a distribution monitoring system for controlled substances. The Oklahoma CSA requires distributor and dispensers of controlled dangerous substances to keep records and maintain inventories in conformance with applicable laws and regulations.

123. The Oklahoma administrative code requires anyone who distributes or dispenses prescription opioid to inform the Oklahoma State Bureau of Narcotics and Dangerous Drugs

Control of suspicious orders. Such orders include those of unusual size or frequency and those deviating substantially from a normal pattern.

124. Likewise, the Oklahoma administrative code requires that distributors and dispensers notify the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control of any theft or significant loss of any controlled dangerous substances. Thefts must be reported whether or not the controlled dangerous substances are subsequently recovered and/or the responsible parties are identified and action taken against them.

125. Distributors and dispensers are also required to maintain records, reports, and inventory in accordance with Oklahoma law, including by complying with their registration and opioid-tracking requirements, which they have not done. Distributors also have a duty to maintain effective controls against diversion of controlled substances.

D. Oklahoma Law Sets a Standard of Care for Pharmacy Defendants to Follow

126. Like manufacturers and distributors, pharmacies must exercise reasonable care under the circumstances. This involves a duty not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative conduct, and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another, is under a duty to exercise reasonable care to prevent the threatened harm.

127. Pharmacists are the "last line of defense" in keeping drugs from entering the illicit market. They are meant to be the drug experts in the healthcare delivery system, and as such have considerable duties and responsibility in the oversight of patient care. They cannot blindly fill prescriptions written by a doctor—even a doctor registered under the Oklahoma CSA to dispense opioids—if the prescription is not for a legitimate medical purpose.

128. The Oklahoma CSA imposes duties and requirements on the conduct of the Pharmacy Defendants. These requirements, along with their related regulations and agency interpretations, set a standard of care for pharmacy conduct.

129. The Oklahoma CSA requires pharmacists to review each opioid prescription and, prior to dispensing medication, determine that the prescription is effective and valid.

130. Under the Oklahoma Administrative Code, pharmacy registrants are required to provide effective controls and procedures to guard against theft and diversion of controlled substances. In addition, the Oklahoma administrative code states: "A prescription for a controlled dangerous substance to be effective must be issued for a legitimate medical purpose by a registered or otherwise authorized individual practitioner acting in the usual course of his/her professional practice. The responsibility for the proper prescribing and dispensing of controlled dangerous substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription, as the filling of a prescription is not incumbent on the pharmacy." Okl. Adm. Code T. 475 Section 30-1-3

131. Therefore, pharmacists are required to ensure that prescriptions for controlled substances are valid, and that they are issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. Additionally, the Pharmacy Defendants must "address the possible addiction or dependency of a patient to a drug dispensed by the pharmacist, if there is reason to believe that the patient may be dependent or addicted," a duty they did not adequately or uniformly perform. Okla. Admin. Code 535:10-3.1.2(12).

132. State pharmacy boards and national industry associations have provided extensive guidance to pharmacists concerning their duties to the public and the standard of care they are expected to meet. The guidance teaches pharmacists how to identify red flags, which indicate

potential problems with a prescription. The guidance also tells pharmacists how to resolve the red flags and what to do if the red flags are unresolvable.

133. The industry guidance tells pharmacists how to recognize stolen prescription pads; prescription pads printed using a legitimate doctor's name, but with a different call-back number that is answered by an accomplice of the drug-seeker; prescriptions written using fictitious patient names and addresses, and so on.

134. Questionable or suspicious prescriptions include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities) for controlled substances than other practitioners in the area; (2) prescriptions which should last for a month in legitimate use, but are being refilled on a shorter basis; (3) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; (4) prescriptions that look "too good" or where the prescriber's handwriting is too legible; (5) prescriptions with quantities or dosages that differ from usual medical usage; (6) prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; (7) photocopied prescriptions; or (8) prescriptions containing different handwritings. Most of the time, these attributes are not difficult to detect or recognize; they should be apparent to an adequately trained pharmacist.

135. Signs that a customer is seeking opioids for the purpose of diversion include customers who: (1) appear to be returning too frequently; (2) are seeking to fill a prescription written for a different person; (3) appear at the pharmacy counter simultaneously, or within a short time, all bearing similar prescriptions from the same physician; (4) are not regular patrons or residents of the community, and show up with prescriptions from the same physician; (5) drive long distances to have prescriptions filled; (6) seek large volumes of controlled substances in the highest strength in each prescription; (7) seek a combination of other drugs with opioids

such as tranquilizers, benzodiazepines, and/or muscle relaxers that can be used to create an "opioid cocktail"; and (8) pay large amounts of cash for their prescriptions rather than using insurance. Other "red flags" include prescriptions that lack the technical requirements of a valid prescription; prescriptions written in excess of the amount needed for proper therapeutic purposes; prescriptions obtained through disreputable or illegal web-based pharmacies; and patients receiving multiple types of narcotic pain killers on the same day.

136. Ignoring these signs violates industry standards and standards required by the "reasonable person" standard under basic principles of Oklahoma tort law.

137. All of these issues have been presented in pharmacist training programs nationwide and have been used as examples by individual state boards of pharmacy and the National Association of Boards of Pharmacy.

138. Industry standards require pharmacists to contact the prescriber for verification or clarification whenever there is a question about any aspect of a prescription order. If a pharmacist is ever in doubt, he or she must ask for proper identification. If a pharmacist believes the prescription is forged or altered, he or she should not dispense it and should call the local police. If a pharmacist believes he or she has discovered a pattern of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

139. A standard of care for the Pharmacy Defendants is also set by Oklahoma statutes and regulations. For example, under Title 59, Section 353.24 of the Oklahoma Statutes, as well as Oklahoma Administrative Code Sections 535:15-3-2, 535:25-9-8, 535:10-3-1.2, pharmacies must "establish and maintain effective controls against the diversion of prescription drugs into other than legitimate medical, scientific, or industrial channels," and it is a violation of professional standards not to attempt to address the suspected addiction of a patient to a drug

dispensed by the pharmacist, if there is reason to believe the patient may be addicted. The Pharmacy Defendants breached duties.

V. DISTRIBUTOR DEFENDANTS AND PHARMACY DEFENDANTS HAVE FAILED TO FULFILL THEIR DUTIES

A. Distributor Defendants Understood Their Duties and Violated Them Anyway

1. Distributor Defendants Understood and Acknowledged Their Duties

140. In addition to state and Federal law and regulations regarding controlled substances, Distributor Defendants received detailed, specific instructions for identifying and minimizing the risk of opioid diversion.

141. To combat opioid diversion, the DEA has provided readily-available guidance to distributors on the requirements of suspicious order reporting.

142. Since 2006, the DEA has briefed distributors regarding legal, regulatory, and due diligence responsibilities. During these briefings, the DEA pointed out the red flags distributors should look for to identify potential diversion.

143. Since 2007, the DEA has hosted at least five conferences to provide registrants with updated information about diversion trends and regulatory changes that affect the drug supply chain and suspicious order reporting.[79] All of the major distributors attended at least one of these conferences.

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[79] Drug Enf't Admin., *Distributor Conferences*, https://www.deadiversion.usdoj.gov/mtgs/distributor/index.html; Drug Enf't Admin., *Manufacturer Conferences*, https://www.deadiversion.usdoj.gov/mtgs/man_imp_exp/index.html; Drug Enf't Admin., *National Conference on Pharmaceutical and Chemical Diversion*, https://www.deadiversion.usdoj.gov/mtgs/drug_chemical/index.html; Drug Enf't Admin., *Diversion Awareness Conferences*, https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/index.html.

144. On September 27, 2006, and December 27, 2007, DEA's Office of Diversion Control sent letters to all registered distributors providing guidance on suspicious order monitoring and the distributors' obligations to conduct due diligence on controlled substance customers to help prevent diversion.[80]

145. The September 27, 2006, letter reminded distributors of their legal obligation to use due diligence to avoid filling orders that might be diverted into the illicit market. The letter explained that each distributor must exercise due care in confirming the legitimacy of all orders. It also described circumstances that could indicate diversion, including ordering (a) excessive quantities of a limited variety of controlled substances while ordering few if any other drugs, or (b) the same controlled substance from multiple distributors.

146. The December 27, 2007, letter reminded distributors that suspicious orders must be reported when discovered and that monthly transaction reports of excessive purchases did not meet the regulatory criteria for suspicious order reporting. The letter also advised distributors that they must independently analyze a suspicious order before the sale to determine if the controlled substances would likely be diverted and that filling a suspicious order and then completing the sale does not absolve the distributor from legal responsibility.

147. Distributor Defendants were on notice that their own industry group, the Healthcare Distribution Management Association ("HDMA"), published Industry Compliance Guidelines for reporting suspicious orders and preventing diversion.[81]

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[80] Masters Pharmaceuticals, Inc.; Decision and Order, 80 Fed. Reg. 55,418, 55,421 (Drug Enf't Admin. Sept. 15, 2015) (No. 13–39), 2015 WL 5320504.

[81] Healthcare Distrib. Mgmt. Ass'n (HDMA), *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App. B at 1).

148. These industry guidelines further explained that, by being "[a]t the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers."[82]

149. Opioid distributors have themselves recognized the magnitude of the problem and have made statements assuring the public they recognize their duty to curb the opioid epidemic.

150. A Cardinal executive recently claimed that Cardinal uses "advanced analytics" to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[83]

151. McKesson has publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and is "deeply passionate about curbing the opioid epidemic in our country."[84]

152. At the very least, these assurances created a duty for Distributor Defendants to act reasonably by following through on them.

2. Prior Regulatory Actions Against Distributor Defendants for Failing to Prevent Diversion

153. Despite knowing the risks of diversion and their broad assurances to regulators, states, and the public, Distributor Defendants have recklessly or negligently allowed diversion. Their misconduct has resulted in numerous civil fines and other penalties.

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[82] *Id.*
[83] Lenny Bernstein et al., *How Drugs Intended for Patients Ended up in the Hands of Illegal Users: 'No One Was Doing Their Job'*, Wash. Post, Oct. 22, 2016, http://wapo.st/2vCRGLt.
[84] Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post, Dec. 22, 2016, http://wapo.st/2uR2FDy.

a. Cardinal

154. Cardinal has paid millions of dollars in multiple DEA and state actions relating to its improper management and distribution of opioids.

155. In 2008, Cardinal paid a $34 million penalty to settle allegations about opioid diversion taking place at seven warehouses around the United States.[85] These allegations included failing to report to the DEA thousands of suspicious orders of hydrocodone that Cardinal then distributed to pharmacies that filled illegitimate prescriptions originating from rogue Internet pharmacy websites.

156. In 2012, Cardinal reached another settlement with the DEA relating to systemic opioid diversion in its Florida distribution center.[86] Cardinal's Florida center received a two-year license suspension for supplying more than 12 million dosage units to only four area pharmacies, nearly 50 times as much oxycodone as it shipped to the rest of Florida and an increase of 241% in only two years. The DEA found that Cardinal's own investigator warned Cardinal against selling opioids to these pharmacies but that Cardinal did nothing to notify the DEA or cut off the supply of drugs to the suspect pharmacies. Instead, Cardinal's opioid shipments to the pharmacies increased.

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[85] Press Release, U.S. Attorney's Office Dist. of Colo., Cardinal Health Inc., Agrees to Pay $34 Million to Settle Claims That it Failed to Report Suspicious Sales of Widely-Abused Controlled Substances (Oct. 2, 2008), https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html.

[86] Press Release, Drug Enf't Admin., DEA Suspends for Two Years Pharmaceutical Wholesale Distributor's Ability to Sell Controlled Substances from Lakeland, Florida Facility (May 15, 2012), https://www.dea.gov/pubs/pressrel/pr051512.html.

157. In December 2016, Cardinal paid $44 million to settle charges that it had violated the law by failing to report suspicious orders in four states.[87] The same Florida distribution center at the heart of the 2012 settlement was again implicated in this case. The settlement also covered a Cardinal subsidiary, Kinray, LLC, which did not report a single suspicious order regarding its shipments of oxycodone and hydrocodone to more than 20 New York-area pharmacy locations that placed unusually high orders of controlled substances at an unusually frequent rate. Cardinal Health d/b/a Kinray is a licensed wholesale drug distributor in Oklahoma and, on information and belief, distributes opioids in the State.

158. In January 2017, Cardinal paid $20 million to settle allegations by West Virginia that Cardinal had shipped increasing amounts of opioids to numerous counties without utilizing proper controls, in essence benefitting from West Virginia's problem with opioid abuse.[88]

b. McKesson

159. McKesson has agreed to pay over $163 million to resolve government charges regarding diversion.

160. In May 2008, McKesson paid $13.25 million to settle claims by the DEA that it had failed to maintain effective controls against diversion.[89] McKesson allegedly failed to report

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[87] Press Release, U.S. Attorney's Office Dist. of Md., Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act (Dec. 23, 2016), https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act.

[88] Eric Eyre, *2 Drug Distributors to Pay $36M to Settle WV Painkiller Lawsuits*, Charleston Gazette-Mail, Jan. 9, 2017, http://www.wvgazettemail.com/news-cops-and-courts/20170109/2-drug-distributors-to-pay-36m-to-settle-wv-painkiller-lawsuits.

[89] Press Release, U.S. Attorney's Office Dist. of Colo., McKesson Corporation Agrees to Pay More than $13 Million to Settle Claims That it Failed to Report Suspicious Sales of Prescription Medications (May 2, 2008), https://www.justice.gov/archive/usao/co/news/2008/May08/5_2b_08.html.

suspicious orders from rogue Internet pharmacies, resulting in millions of doses of controlled substances being diverted.

161. Following the 2008 settlement, McKesson was supposed to change its ways and fix its flawed processes to prevent opioid diversion. But it did not do so. It was later revealed that McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that, in a five-year period, it filled more than 1.6 million orders but reported just 16 orders as suspicious (all from a single consumer). In early 2017, it was reported that McKesson had agreed to pay $150 million to the federal government to settle certain opioid diversion claims that it allowed drug diversion at 12 distribution centers in 11 states.[90]

c. AmerisourceBergen

162. AmerisourceBergen has paid $16 million in settlements and had certain licenses revoked as a result of allegations related to opioid diversion.

163. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies.[91] Again in 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels.[92]

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[90] Press Release, U.S. Dep't of Justice, McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs (Jan. 17, 2017), https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders.

[91] Press Release, AmerisourceBergen, AmerisourceBergen Signs Agreement with DEA Leading to Reinstatement of Its Orlando Distribution Center's Suspended License to Distribute Controlled Substances (June 22, 2007), http://investor.amerisourcebergen.com/news-releases/news-release-details/amerisourcebergen-signs-agreement-dea-leading-reinstatement-its.

[92] Jeff Overley, *AmerisourceBergen Subpoenaed by DEA over Drug Diversion*, LAW360 (Aug. 9, 2012, 4:28 PM), https://www.law360.com/articles/368498/amerisourcebergen-subpoenaed-by-dea-over-drug-diversion.

164. In January 2017, AmerisourceBergen paid the State of West Virginia $16 million to settle allegations that it knowingly shipped increasing amounts of opioids without sufficient monitoring or control, facilitating six-fold increases in opioid consumption in some counties.[93] AmerisourceBergen was part of a drug supply chain that included doctors who wrote prescriptions for non-medical purposes and "pill mill" pharmacies that dispensed excessive numbers of painkillers. In addition to the monetary settlement, AmerisourceBergen agreed to adhere to stricter reporting guidelines within West Virginia.

3. Despite Prior Regulatory Actions, Distributor Defendants Violated Their Duties in Oklahoma

165. Despite being penalized by law enforcement authorities, Distributor Defendants have not changed their conduct. Rather, they have treated fines as a cost of doing business in an industry that generates billions of dollars in revenue.

166. All of the Distributor Defendants have engaged in a consistent, nationwide pattern and practice of illegally distributing opioids. That pattern and practice has also affected the Nation and its citizens.

167. In fact, Distributor Defendants have supplied and continue to supply prescription opioids on and around the Nation with actual or constructive knowledge that they were ultimately being consumed by Nation citizens for non-medical purposes. Many of these shipments should have been stopped or investigated as suspicious orders, but Distributor Defendants negligently or recklessly failed to do so.

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[93] Eric Eyre, *2 Drug Distributors to Pay $36M to Settle WV Painkiller Lawsuits*, Charleston Gazette-Mail, Jan. 9, 2017, http://www.wvgazettemail.com/news-cops-and-courts/20170109/2-drug-distributors-to-pay-36m-to-settle-wv-painkiller-lawsuits.

168. Each Distributor Defendant knew, or should have known, that the amount of opioids that it allowed to flow into the Nation far exceeded what could be consumed for medically necessary purposes.

169. Distributor Defendants negligently or recklessly failed to control their supply lines to prevent diversion. A reasonably prudent distributor of controlled substances would have anticipated the danger of opioid diversion and protected against it by, for example: (a) taking greater care in hiring, training, and supervising employees; (b) providing greater oversight, security, and control of supply channels; (c) looking more closely at pharmacists and doctors who were purchasing large quantities of commonly-abused opioids in amounts much greater than appropriate, given the size of the local populations; (d) investigating demographic or epidemiological facts concerning the increasing demand for narcotic painkillers on and around the Nation; (e) informing pharmacies and retailers about opioid diversion; and (f) following statutes, regulations, professional standards, and guidance from government agencies.

170. On information and belief, Distributor Defendants made little to no effort to visit pharmacies servicing the Nation to perform inspections to ensure that the controlled substances Distributor Defendants had furnished were not being diverted to illegal uses.

171. On information and belief, the compensation Distributor Defendants provided to certain of their employees was affected, in part, by the volume of their sales of opioids to pharmacies and other facilities servicing the Nation, thus improperly creating incentives that exacerbated opioid diversion and the resulting epidemic of opioid abuse.

B. Pharmacy Defendants Understood Their Duties and Violated Them Anyway

1. Pharmacy Defendants Understood and Acknowledged Their Duties

172. Pharmacy Defendants similarly knew of the risks and harms of filling prescriptions for non-medical purposes, including widespread opioid abuse.

173. The DEA has provided extensive guidance to pharmacists concerning their duties to the public.[94] So have state pharmacy boards[95] and national industry associations.[96] The guidance teaches pharmacists how to identify red flags, which indicate that there may be a problem with the legitimacy of a prescription presented by a patient.[97] The guidance also tells pharmacists how to resolve the red flags and what to do if the red flags are unresolvable.

174. For instance, the industry guidance tells pharmacists how to recognize: (a) stolen prescription pads; (b) prescription pads printed using a legitimate doctor's name, but with a different call back number that is answered by an accomplice of the drug-seeker; (c) prescriptions written using fictitious patient names and addresses; and (d) other red flags.[98]

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[94] Michele Leonhart et al., *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act*, Drug Enf't Admin., Diversion Control Div. (Revised 2010), https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/.

[95] Tex. State Bd. of Pharmacy, *Abuse & Misuse of Prescription Drugs* (last visited Mar. 26, 2018), https://www.pharmacy.texas.gov/SB144.asp; Fla. Bd. of Pharmacy, *DEA Guidelines to Prescription Fraud* (June 12, 2013), http://floridaspharmacy.gov/latest-news/dea-guidelines-to-prescription-fraud/; Va. Bd. of Pharmacy, *Prescription Drug Abuse: Red Flags for Pharmacists and Pharmacy Technicians* (Aug. 6, 2014), https://youtu.be/j5CkhirlZk8.

[96] Philip Brummond et al., *American Society of Health-Systems Pharmacists Guidelines on Preventing Diversion of Controlled Substances*, 74 Am. J. of Health-Sys. Pharmacy e10 (Jan. 2017), http://www.ajhp.org/content/early/2016/12/22/ajhp160919.

[97] Va. Bd. of Pharmacy, *Prescription Drug Abuse: Red Flags for Pharmacists and Pharmacy Technicians* (Aug. 6, 2014), https://youtu.be/j5CkhirlZk8; Philip W. Brummond et al., *American Society of Health-Systems Pharmacists Guidelines on Preventing Diversion of Controlled Substances*, 74 Am. J. of Health-System Pharmacy e10 (Jan. 2017), http://www.ajhp.org/content/early/2016/12/22/ajhp160919.

[98] Fla. Bd. of Pharmacy, *DEA Guidelines to Prescription Fraud* (June 12, 2013), http://floridaspharmacy.gov/latest-news/dea-guidelines-to-prescription-fraud/; Mass. Bd. of

175. Pharmacy Defendants, through their words or actions set forth in news reports and other public documents, have acknowledged these risks and assured the public that issues affecting public health and safety are their highest priority.

176. In 2015, CVS publicly stated that, "the abuse of controlled substance pain medication is a nationwide epidemic that is exacting a devastating toll upon individuals, families and communities. Pharmacists have a legal obligation under Oklahoma and Federal law to determine whether a controlled substance was issued for a legitimate purpose and to decline to fill prescriptions they have reason to believe were issued for a non-legitimate purpose."[99]

177. Similarly, in 2016, Walgreens issued a press release captioned "Walgreens Leads Fight Against Prescription Drug Abuse with New Programs to Help Curb Misuse of Medications and the Rise in Overdose Deaths."[100]

178. In 2017, Walmart acknowledged the need for a "solution to the [opioid] epidemic" and noted the epidemic has "devastated so many families and communities across America."[101]

Registration in Med., Policy 15-05, *Prescribing Practices Policy and Guidelines* (Oct. 8, 2015), http://www.mass.gov/eohhs/docs/borim/policies-guidelines/policy-15-05.pdf.

[99] *Patients Profiled at Pharmacy Counters*, KTNV, Feb. 23, 2015, http://contact1846.rssing.com/chan-30860085/all_p11.html#item217.

[100] Press Release, Walgreens, Walgreens Leads Fight Against Prescription Drug Abuse with New Programs to Help Curb Misuse of Medications and the Rise in Overdose Deaths (Feb. 9, 2016), http://news.walgreens.com/press-releases/general-news/walgreens-leads-fight-against-prescription-drug-abuse-with-new-programs-to-help-curb-misuse-of-medications-and-the-rise-in-overdose-deaths.htm.

[101] Press Release, Walmart, Walmart Supports State of Emergency Declaration on Opioids (Oct. 26, 2017), https://news.walmart.com/2017/10/26/walmart-supports-state-of-emergency-declaration-on-opioids.

2. Prior Regulatory Actions Against Pharmacy Defendants for Failing to Prevent Diversion

179. Despite knowing and even warning of these risks, Pharmacy Defendants recklessly or negligently permitted diversion to occur. In failing to take adequate measures to prevent substantial opioid-related injuries to the Nation, Pharmacy Defendants have breached their duties under the "reasonable care" standard of Oklahoma common law (including violating a voluntarily-undertaken duty to the public which they have assumed by their own words and actions), professional duties under the relevant standards of professional practice, and requirements established by Oklahoma laws and regulations.

180. Pharmacy Defendants were on notice of their ongoing negligence or reckless misconduct towards the Nation in part because of their history of being penalized for violating their duties in other jurisdictions.

a. CVS

181. CVS has paid fines totaling over $40 million as the result of a series of investigations by the DEA and the United States Department of Justice ("DOJ"). It nonetheless treated these fines as the cost of doing business and has allowed its pharmacies to continue (a) dispensing opioids in quantities significantly higher than any plausible medical need would require, and (b) violating their recordkeeping and dispensing obligations.

182. As recently as February 2016, CVS paid $8 million to settle allegations by the DEA and the DOJ that its stores and pharmacists had been violating their legal duties and filling prescriptions with no legitimate medical purpose.[102] CVS has resolved similar allegations by

[102] Press Release, Drug Enf't Admin., DEA Reaches $8 Million Settlement Agreement with CVS for Unlawful Distribution of Controlled Substances (Feb. 12, 2016), https://www.dea.gov/divisions/wdo/2016/wdo021216.shtml.

settling with Florida ($22 million),[103] Oklahoma ($11 million),[104] Massachusetts and New Hampshire ($3.5 million),[105] Texas ($1.9 million),[106] and Rhode Island ($450,000).[107]

183. These cases included evidence that CVS filled prescriptions that were clearly forged. For example, in 2016, CVS settled with the United States to resolve allegations stemming from two DEA investigations that revealed that over 50 CVS stores in Massachusetts and New Hampshire had filled patently forged prescriptions for addictive painkillers more than 500 times between 2011 and 2014.[108] The DEA estimated the street value of the diverted drugs to be over $1 million. One forger successfully filled 131 prescriptions for hydrocodone at eight CVS stores. One of those stores filled 29 prescriptions for the forger over the course of just six months, an inordinate amount under the circumstances. At a different store, the same individual

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[103] Press Release, U.S. Attorney's Office Middle Dist. of Fla., United States Reaches $22 Million Settlement Agreement with CVS for Unlawful Distribution of Controlled Substances (May 13, 2015), https://www.justice.gov/usao-mdfl/pr/united-states-reaches-22-million-settlement-agreement-cvs-unlawful-distribution.

[104] Press Release, U.S. Attorney's Office W. Dist. of Okla., CVS to Pay $11 Million to Settle Civil Penalty Claims Involving Violations of Controlled Substances Act (Apr. 3, 2013), https://www.justice.gov/usao-wdok/pr/cvs-pay-11-million-settle-civil-penalty-claims-involving-violations-controlled.

[105] Press Release, U.S. Attorney's Office Dist. of Mass., CVS to Pay $3.5 Million to Resolve Allegations That Pharmacists Filled Fake Prescriptions (June 30, 2016), https://www.justice.gov/usao-ma/pr/cvs-pay-35-million-resolve-allegations-pharmacists-filled-fake-prescriptions.

[106] Patrick Danner, *H-E-B, CVS Fined over Prescriptions*, San Antonio Express-News, Sept. 5, 2014, http://www.expressnews.com/business/local/article/H-E-B-CVS-fined-over-prescriptions-5736554.php.

[107] Press Release, U.S. Attorney's Office Dist. of R.I., Drug Diversion Claims Against CVS Health Corp. Resolved with $450,000 Civil Settlement (Aug. 10, 2015), https://www.justice.gov/usao-ri/pr/drug-diversion-claims-against-cvs-health-corp-resolved-450000-civil-settlement.

[108] Press Release, U.S. Attorney's Office Dist. of Mass., CVS to Pay $3.5 Million to Resolve Allegations That Pharmacists Filled Fake Prescriptions (June 30, 2016), https://www.justice.gov/usao-ma/pr/cvs-pay-35-million-resolve-allegations-pharmacists-filled-fake-prescriptions.

filled 28 forged prescriptions, even though they were identical in every respect other than the patient name. Additionally, 107 of the forged prescriptions bore the Massachusetts address of a dentist who had closed her Massachusetts practice and moved to Maine, something that should have been easily discovered by CVS pharmacists by checking the DEA website or calling the phone number on the prescriptions.

184. CVS also paid $8 million to settle allegations by the DEA and the DOJ that its stores and pharmacists had been violating their legal duties and filling prescriptions with no legitimate medical purpose.[109] As part of the settlement, CVS acknowledged that from 2008 to 2012, some of its stores in Maryland dispensed controlled substances, including opioids, in a manner that was not fully consistent with its legal obligations, including failing to comply with the responsibility to ensure that these prescriptions were issued for a legitimate medical purpose.

185. CVS also paid $600,000 to settle allegations by the DOJ that on over 6,000 occasions, CVS stores in Connecticut failed to keep appropriate records of prescriptions and purchase invoices.[110]

186. Dating back to 2006, CVS pharmacies in Oklahoma and elsewhere intentionally violated the law by filling prescriptions signed by prescribers with invalid DEA registration numbers.[111] To fill otherwise illegitimate prescriptions, CVS pharmacists substituted valid DEA

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[109] Press Release, U.S. Attorney's Office Dist. of Md., United States Reaches $8 Million Settlement Agreement with CVS for Unlawful Distribution of Controlled Substances (Feb. 12, 2016), https://www.justice.gov/usao-md/pr/united-states-reaches-8-million-settlement-agreement-cvs-unlawfuldistribution-controlled.

[110] Press Release, U.S. Attorney's Office Dist. of Conn., CVS Pharmacy Pays $600,000 to Settle Controlled Substances Act Allegations (Oct. 20, 2016), https://www.justice.gov/usao-ct/pr/cvs-pharmacy-pays-600000-settle-controlled-substances-act-allegations.

[111] Press Release, U.S. Attorney's Office W. Dist. of Okla., CVS to Pay $11 Million to Settle Civil Penalty Claims Involving Violations of Controlled Substances Act (Apr. 3, 2013),

registration numbers of non-prescribing practitioners, or substituted false DEA registration numbers in company computer systems, on paper prescriptions, and even in the information that the pharmacy reported to Oklahoma's Prescription Drug Monitoring Program.[112]

b. Walgreens

187. Walgreens agreed to the largest settlement in DEA history—$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the FCSA, including negligently allowing controlled substances such as oxycodone and other prescription pain killers to be diverted for abuse and illegal black market sales.[113] As part of the settlement, Walgreens agreed to enhance its training and compliance programs, and to cease compensating its pharmacists based on the volume of prescriptions filled.

188. Walgreens' Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than 10 times the average amount.[114] They increased their orders over time, in some cases as much as 600% in the span of just two years, including, for example, supplying a town of 3,000 residents with 285,800 orders of oxycodone in a one-month period. Yet Walgreens' corporate officers not only turned a blind eye, but also facilitated the opioid boom in Florida by providing Walgreens'

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https://www.justice.gov/usao-wdok/pr/cvs-pay-11-million-settle-civil-penalty-claims-involving-violations-controlled.

[112] *See* Complaint, *United States v. CVS Pharmacies*, No. 5:11-cv-1124-HE (W.D. Okla. Oct. 5, 2011).

[113] Press Release, U.S. Attorney's Office S. Dist. of Fla., Walgreens Agrees to Pay a Record Settlement of $80 Million for Civil Penalties Under the Controlled Substances Act (June 11, 2013), https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under-controlled.

[114] Order to Show Cause and Immediate Suspension of Registration, *In the Matter of Walgreen Co.* (Drug Enf't Admin. Sept. 13, 2012).

pharmacists with incentives through a bonus program that compensated them based on the number of prescriptions filled at the pharmacy. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that "if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance," underscoring Walgreens' attitude that profit outweighed compliance with the law or the health of communities.[115]

189. Walgreens has also settled with a number of state attorneys general, including West Virginia ($575,000)[116] and Massachusetts ($200,000).[117] The Massachusetts Attorney General's Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high-risk. Such patients are supposed to obtain all prescriptions from only one pharmacy, and that pharmacy is required to track the patient's pattern of prescription use. Some of the state's 160 Walgreens accepted cash for controlled substances from patients in MassHealth (the state's combined program for Medicaid and Children's Health Insurance Program), rather than seeking approval from the agency. In some cases, MassHealth had rejected the prescription; other times, MassHealth was never billed. In response, Walgreens simply agreed to update its policies and procedures and train its staff to ensure that pharmacists properly monitor and do not accept cash payments from patients deemed high-risk.

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[115] *Id.*

[116] Caleb Stewart, *Kroger, CVS, and Walgreens Settle Lawsuit with West Virginia for $3 Million*, WHSV, Aug. 16, 2016, http://www.whsv.com/content/news/Kroger-CVS-and-Walgreens-settle-lawsuit-with-West-Virginia-for-3-million-390332992.html.

[117] Felice J. Freyer, *Walgreens to Pay $200,000 Settlement for Lapses with Opioids*, The Boston Globe, Jan. 19, 2017, https://www.bostonglobe.com/metro/2017/01/18/walgreens-agrees-better-monitor-opioid-dispensing/q0B3FbMo2k3wPt4hvmTQrM/story.html.

c. Walmart

190. In 2009, Walmart paid $637,000 to resolve allegations of numerous record keeping violations at its pharmacies in Texas. Those allegations included that Walmart had failed to timely file records indicating loss or theft of drugs to the DEA, in violation of the FCSA.[118]

3. Despite Prior Regulatory Actions, Pharmacy Defendants Continue to Violate Their Duties

191. Despite their extensive understanding of the risks and harms of opioid diversion, Pharmacy Defendants continue to fail to fulfill their obligations to prevent opioid diversion.

192. Pharmacy Defendants have engaged in a consistent, nationwide pattern and practice of illegally distributing opioids that has also affected the Nation and its citizens.

193. On information and belief, Pharmacy Defendants regularly filled prescriptions in circumstances where red flags were present.

194. On information and belief, Pharmacy Defendants regularly filled opioid prescriptions that would have been questioned by a reasonably prudent pharmacy.

195. On information and belief, Pharmacy Defendants have not adequately trained or supervised their employees at the point of sale to investigate or report suspicious or invalid prescriptions, or protect against corruption or theft by employees or others.

196. On information and belief, Pharmacy Defendants utilize monetary compensation programs for certain employees that are based, in part, on the number of prescriptions filled and

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[118] *See generally* Emma Perez-Trevino, *Wal-Mart Fined for Alleged Recording Keeping Violations*, Brownsville Herald, Jan. 7, 2009, http://www.brownsvilleherald.com/news/local/article_1a19f348-e9ad-534f-a1a1-8423736b0df9.html; *Walmart Fined for Pharmacy Record-Keeping Violations*, Ozarks First, Jan. 7, 2009, http://www.ozarksfirst.com/news/health-and-medical/walmart-fined-for-pharmacy-record-keeping-violations

dispensed. This type of compensation creates economic disincentives within the companies to change their practices. For example, there have been reports of chain store supervisory personnel directing pharmacists to fill prescriptions regardless of the red flags presented.

VI. DEFENDANTS' MISCONDUCT HAS INJURED AND CONTINUES TO INJURE THE NATION AND ITS CITIZENS

197. Defendants had the ability and the duty to prevent misleading marketing and opioid diversion, both of which presented known or foreseeable dangers of serious injury. But they failed to do so, resulting in substantial injury to the Nation and its citizens.

A. Manufacturer Defendants' Misconduct Has Injured and Continues to Injure the Nation and Its Citizens

198. Manufacturer Defendants' marketing campaign has resulted in a significant increase in opioid usage: between 1999 and 2016 the number of opioids prescribed nationwide quadrupled.[119] Nationally, the number of people who take prescription opioids for non-medical purposes is now greater than the number of people who use cocaine, heroin, hallucinogens, and inhalants combined.[120]

199. Every year, millions of Americans abuse opioid pain relievers, leading to addiction, overdose, and death. Data from the CDC suggest that over 2.6 million Americans are opioid-dependent and over 16.5 million use prescription opioids for non-medical purposes.

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[119] Li Hui Chen et al., *Drug-Poisoning Deaths Involving Opioid Analgesics: United States, 1999–2011*, 166 Nat'l Ctr. for Health Statistics Data Brief (Sept. 2014), https://www.cdc.gov/nchs/data/databriefs/db166.pdf; Rose A. Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015*, 65 Morbidity and Mortality Weekly Report 1445 (Dec. 30, 2016), https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm.

[120] Substance Abuse and Mental Health Servs. Admin., *Results from the 2009 National Survey on Drug Use and Health: Volume I. Summary of National Findings*, NSDUH Series H-38A, HHS Publication No. SMA 10-4586 Findings (2010).

200. In 2017 alone, data from the Substance Abuse and Mental Health Services Administration indicate that over 194,000 residents use prescription opioids for non-medical purposes.[121] Similarly, DEA data shows that in 2016, Oklahoma has seen annual distribution exceeding 660 milligrams per resident,[122] and 5,923 milligrams per opioid user,[123] which is far more than is medically necessary.

201. This growth in non-medical demand, addiction, and diversion has led to serious harm to the Nation and its citizens. The increase in opioid usage has led to levels of addiction that, according to the U.S. Surgeon General, have "devastated" communities across America.[124] Princeton University economist Alan Krueger found that opioids may be responsible for roughly 20% of the national decline in workforce participation by prime-age men and 25% of the drop by women.[125] In 2011, the CDC reported that overdose deaths from prescription opioids had reached "epidemic levels."[126] That year, 16,917 people died from a prescription opioid-related

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[121] Substance Abuse and Mental Health Servs. Admin., *National Survey on Drug Use and Health: Comparison of 2002–2003 and 2013–2014 Population Percentages (50 States and the District of Columbia)* 16–17 (2015), http://www.samhsa.gov/data/sites/default/files/NSDUHsaeLongTermCHG2014/NSDUHsaeLongTermCHG2014.pdf.

[122] Drug Enf't Admin., ARCOS Report, *Retail Drug Distribution By Zip Code Within State by Grams Weight*, https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/2013/2013_rpt1.pdf; https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/2014/2014_rpt1.pdf; https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/2015/2015_rpt1.pdf; https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/report_yr_2016.pdf.

[123] Wenjun Zhong et al., *Age and Sex Patterns of Drug Prescribing in a Defined American Population*, 7 Mayo Clinic Proceedings 697, 700 (2013).

[124] Letter from U.S. Surgeon General Vivek H. Murthy (Aug. 2016), https://perma.cc/VW95-CUYC.

[125] *See* Alan B. Krueger, *Where Have All the Workers Gone? An Inquiry into the Decline of the U.S. Labor Force Participation Rate*, Brookings Papers on Econ. Activity Conference Draft (Aug. 26, 2017).

[126] Press Release, CDC, Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.

overdose—an increase of more than 20% over the previous three years.[127] Since then, the national death toll has continued to rise. In 2014, 18,893 people died from a prescription opioid-related overdose.[128] In 2015, that number increased again to 22,598.[129] As discussed above, overdose deaths in the United States involving prescription opioids have quadrupled since 1999. CDC data shows that over 123,095 people died from prescription opioid overdoses from 2011–2016.[130]

202. It was reasonably foreseeable to Manufacturer Defendants that their deceptive and aggressive marketing of opioids on and around the Nation would allow opioids to fall into the hands of addicts and other inappropriate users.

203. It was reasonably foreseeable to Manufacturer Defendants that their deceptive, unfair, and false marketing campaigns would cause injuries, including abuse, addiction, overdoses, and death. It was also reasonably foreseeable that many of these injuries would be suffered by the Nation and its citizens, and that the costs of these injuries would be shouldered by the Nation.

204. Manufacturer Defendants knew or should have known that their continuing efforts to employ deceptive, unfair, and false marketing, despite being previously sanctioned by government agencies for such actions, would contribute to the opioid epidemic affecting the Nation.

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[127] Li Hui Chen et al., *Drug-poisoning Deaths Involving Opioid Analgesics: United States, 1999–2011*, 166 Nat'l Ctr. for Health Statistics Data Brief (Sept. 2014), https://www.cdc.gov/nchs/data/databriefs/db166.pdf.
[128] Rose A. Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015*, 65 Morbidity and Mortality Weekly Report 1445 (Dec. 30, 2016), https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm.
[129] *Id.*
[130] CDC, Wide-ranging Online Data for Epidemiologic Research (WONDER), http://wonder.cdc.gov.

205. Manufacturer Defendants knew or should have known that a substantial amount of the opioids dispensed on and around the Nation were being dispensed as a result of their deceptive, unfair, and false marketing. It was foreseeable that the increased number of prescriptions for opioids resulting from Manufacturer Defendants' deceptive, unfair, and false marketing would cause harm to individual pharmacy customers, third parties, and the Nation.

206. Manufacturer Defendants made substantial profits over the years based on the deceptive, unfair, and false marketing of opioids on and around the Nation. Their participation and cooperation in a common enterprise has foreseeably caused damages to the Nation and injuries to its citizens. Manufacturer Defendants knew or should have known that the Nation would be unjustly forced to bear the costs of these injuries and damages.

207. Manufacturer Defendants' deceptive, unfair, and false marketing of prescription opioids to the Nation showed a reckless disregard for the safety of the Nation and its citizens. Their conduct poses a continuing threat to the health, safety, and welfare of the Nation and its citizens.

B. Distributor Defendants' Misconduct has Injured and Continues to Injure the Nation and Its Citizens

208. It was reasonably foreseeable to Distributor Defendants that their violations of their duties under Federal and Oklahoma law and regulations would allow opioids to be diverted.

209. It was reasonably foreseeable to Distributor Defendants that their failure to prevent diversion would cause injuries, including addiction, overdoses, and death. It was also reasonably foreseeable that many of these injuries would be suffered by the Nation and its citizens, and that the costs of these injuries would be shouldered by the Nation.

210. Distributor Defendants knew or should have known that the opioids being diverted from their supply chains would contribute to the Nation's opioid epidemic, and would

create access to opioids by unauthorized users, which, in turn, would perpetuate the cycle of addiction, demand, and illegal transactions.

211. Distributor Defendants knew or should have known that a substantial amount of the opioids dispensed on and around the Nation were being dispensed based on invalid or suspicious prescriptions. It was foreseeable that filling suspicious orders for opioids would harm the Nation and its citizens.

212. Distributor Defendants knew of widespread prescription opioid abuse on and around the Nation, but nevertheless persisted in a pattern of distributing commonly-abused and diverted opioids in places—and in such quantities, and with such frequency—that they knew or should have known these opioids were not being prescribed and consumed for legitimate medical purposes.

213. The use of opioids by the Nation's citizens who were addicted or who did not have a medically necessary purpose for using opioids could not have occurred without the actions of Distributor Defendants. If Distributor Defendants had guarded against diversion as required by Oklahoma law, the Nation and its citizens would have avoided significant injury.

214. Distributor Defendants profited substantially from the illegal diversion of prescription opioids in the Nation. Distributor Defendants' participation and cooperation in a common enterprise has foreseeably caused injuries to the Nation's citizens and financial damages to the Nation. Distributor Defendants knew or should have known that the Nation would be unjustly forced to bear the costs of these injuries.

215. Distributor Defendants' distribution of excessive amounts of prescription opioids in the Nation showed a reckless disregard for the safety of the Nation and its citizens.

Distributor Defendants' conduct poses a continuing threat to the health, safety, and welfare of the Nation and its citizens.

216. At all relevant times, Distributor Defendants engaged in these activities, and continue to do so, knowing that the Nation in its role of providing protection and care for its citizens, would have to provide or pay for additional costs to the healthcare, criminal justice, social services, welfare, and education systems, and would also have to bear the loss of substantial economic productivity and tax revenue.

217. It was reasonably foreseeable to Distributor Defendants that the Nation would be forced to bear substantial expenses as a result of Distributor Defendants' acts.

218. The conduct of Distributor Defendants, their agents, and their employees was, at the very least, negligent.

C. Pharmacy Defendants' Misconduct Has Injured and Continues to Injure the Nation and Its Citizens

219. It was reasonably foreseeable to Pharmacy Defendants that filling invalid or suspicious prescriptions for opioids would cause harm to the Nation and its citizens.

220. It was reasonably foreseeable to Pharmacy Defendants that their failure to prevent diversion would cause injuries, including addiction, overdoses, and death. It was also reasonably foreseeable many of these injuries would be suffered by the Nation and its citizens.

221. Pharmacy Defendants were aware of widespread prescription opioid abuse on and around the Nation, but nevertheless persisted in filling invalid or suspicious prescriptions for opioids and failed to address this misconduct.

222. The use of opioids by the Nation's citizens who were addicted or who did not have a medically necessary purpose could not have occurred without the actions of Pharmacy

Defendants. If Pharmacy Defendants had guarded against diversion, the Nation and its citizens would have avoided significant injury.

223. Pharmacy Defendants made substantial profits from the diversion of prescription opioids in the Nation. Their participation and cooperation in a common enterprise has foreseeably caused injuries to the Nation's citizens and damages to the Nation. Pharmacy Defendants knew or should have known that the Nation would be unjustly forced to bear the costs of these injuries.

224. At all relevant times, Pharmacy Defendants have engaged in improper dispensing practices, and continue to do so, despite knowing they could take measures to eliminate them in substantial part.

225. At all relevant times, Pharmacy Defendants engaged in these activities, and continue to do so, knowing that the Nation, in its role of providing protection and care for its citizens, would have to provide or pay for additional costs to the healthcare system, justice system, social services, welfare, and education system, and would also have to bear the loss of substantial economic productivity and tax revenue.

226. It was reasonably foreseeable to Pharmacy Defendants that the Nation would be forced to bear substantial expenses as a result of Pharmacy Defendants' acts.

227. The conduct of Pharmacy Defendants, their agents, and their employees is, at the very least, negligent.

D. Defendants' Misconduct Has Damaged the Nation and Its Citizens

228. Defendants' misleading marketing and failure to prevent opioid diversion damaged the Nation and its citizens. Defendants' misconduct has contributed to a range of social problems, including violence and delinquency. Adverse social outcomes include child neglect,

family dysfunction, babies born addicted to opioids, criminal behavior, poverty, property damage, unemployment, and social despair. As a result, more and more of the Nation's resources are devoted to addiction-related problems. Meanwhile, the prescription opioid crisis diminishes the Nation's available workforce, decreases productivity, increases poverty, and consequently requires greater expenditures by the Nation.

COUNT I
LANHAM ACT
(Against All Defendants)

229. The Nation realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

230. The Lanham Act provides, in pertinent part:

> (1) Any person who, on or in connection with any goods or services…uses in commerce any . . . false or misleading description of fact, or false or misleading representation of fact, which –
>
> (B) in commercial advertising or promotion, misrepresents the nature, characteristics [or] qualities . . . of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

231. As alleged in Paragraphs 1–227 of this Complaint, Defendants, in connection with their manufacture, distribution, and/or sale of prescription opioids, made numerous false or misleading descriptions and representations of fact.

232. These false or misleading descriptions and representations of fact occurred during Defendants' advertising and promotion of prescription opioids.

233. These false or misleading descriptions and representations of fact misrepresented the nature, characteristics, or qualities of the prescription opioids.

234. Specifically, as described herein, Manufacturer Defendants misrepresented the safety and efficacy of prescription opioids.

235. Distributor Defendants and Pharmacy Defendants misleadingly represented that they were taking effective steps to prevent diversion.

236. The Nation was damaged by Defendants' false or misleading descriptions and representations of fact.

237. For instance, Defendants' false or misleading descriptions and representations of fact diverted patients from hospitals and clinics run by the Nation, instead seeking care from doctors and clinics who prescribed high doses of opioids. But for Defendants' false advertising as to the safety of opioid drugs, these patients would have sought alternative, safer forms of treatment offered by the Nation's hospitals and clinics.

238. Similarly, Defendants' false or misleading descriptions and representations of fact diverted the Nation's citizens and other patients from drug treatment services, including those provided by the Nation. But for Defendants' false advertising as to the safety of prescription opioids and Defendants' claims of "pseudoaddiction," more of the Nation's citizens and other patients would have sought services from the Nation's clinics and other treatment facilities, and would have successfully recovered from opioid addiction.

239. The Defendants engaged in a false and misleading advertising campaign designed to deceive doctors and the public into believing that opioids were safe for the treatment of chronic pain.

240. As alleged herein, and incorporated into this count, the Defendants engaged in systemic false and misleading advertising, via print advertising, promotional materials, and other items designed to reach consumers.

241. The Nation is entitled to legal and equitable relief, including injunctive relief, disgorgement, and damages in an amount to be determined.

COUNT II
NUISANCE
(Against Manufacturer Defendants)

242. The Nation realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

243. Manufacturer Defendants have caused, are causing, and will continue to cause a public nuisance, in that they have committed offenses against the public order and economy of the Nation by unlawfully marketing prescription opioids through misleading statements in ways that facilitate the sale, distribution, and dispensing of such drugs from premises on and around the Nation to unauthorized users in the Nation —including children, people at risk of overdose or suicide, and criminals.

244. Manufacturer Defendants' activities have unreasonably interfered, are interfering, and will interfere with the common rights of the general public:

a. to be free from reasonable apprehension of danger to person and property;

b. to be free from the spread of disease within the community, including the disease of addiction and other diseases associated with widespread illegal opioid use;

c. to be free from the negative health and safety effects of widespread illegal drug sales on premises on and around the Nation;

d. to be free from blights on the community created by areas of illegal drug use and opioid sales;

e. to live or work in a community in which local businesses do not profit from using their premises to sell products that serve the criminal element and foster a secondary market of illegal transactions; and

f. to live or work in a community in which community members are not under the influence of narcotics unless they have a legitimate medical need to use them.

245. Manufacturer Defendants' interference with these public rights has been, is, and will continue to be unreasonable and objectionable because it:

a. has harmed and will continue to harm the public health and public peace of the Nation;

b. has harmed and will continue to harm the Nation's neighborhoods and communities by increasing crime, and thereby interfering with the rights of the community at large;

c. violates statutory and common-law duties;

d. is of a continuing nature, and has produced long-lasting effects; and

e. is known to Manufacturer Defendants that their conduct has a significant effect upon the public rights of the Nation and its citizens.

246. In addition and independently, the Manufacturer Defendants' conduct invades a legally protected interest. Manufacturer Defendants' conduct constitutes an unreasonable, intentional, and substantial interference because, *inter alia*, each Manufacturer Defendant has conducted a fraudulent campaign to misrepresent knowingly the safety and efficacy of opioid drugs and to ensure their widespread use for chronic pain.

247. Because Manufacturer Defendants have marketed and sold prescription opioids in a manner contrary to law and because Manufacturer Defendants' conduct has unreasonably, intentionally, and substantially interfered with a right common to the general public, Manufacturer Defendants are liable for public nuisance.

248. The nuisance has affected the Muscogee community in that it has undermined, is undermining, and will continue to undermine public health, quality of life, and safety of the Nation's citizens. It has resulted in increased crime and property damage within the Nation. It has resulted in high rates of addiction, overdoses, and dysfunction within the Nation's families and communities.

249. The Nation's resources have been, are being, and will be consumed in efforts to address the prescription drug abuse epidemic, thereby eliminating available resources which could be used to benefit the Nation.

250. The Manufacturer Defendants' actions and omissions annoy, injure, and endanger the comfort, repose, health, and safety of the Nation, offend decency, and render the Nation's citizens insecure in their lives and the use of property.

251. Manufacturer Defendants' nuisance-causing activities are not outweighed by their utility. In fact, these activities are illegal and have no social utility whatsoever. There is no legitimately-recognized societal interest in marketing and selling prescription opioids through false and misleading representations.

252. At all times, Manufacturer Defendants possessed the right and ability to control the nuisance-causing flow of prescription opioids into the Nation.

253. As a direct and proximate result of the Manufacturer Defendants' nuisance, the Nation's citizens have been injured in their ability to enjoy rights common to the public.

254. As a direct and proximate result of the nuisance, the Nation has sustained economic harm by spending substantial sums on the societal harms caused by Manufacturer Defendants' nuisance-causing activity, including costs to the healthcare, criminal justice, social services, welfare, and education systems.

255. The Nation has also suffered unique harms of a kind that are different from its citizens at large, namely, that the Nation has been harmed in its proprietary interests.

COUNT III
NEGLIGENCE
(Against Manufacturer Defendants)

256. The Nation realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

257. Manufacturer Defendants owe a duty to the Nation to act reasonably under the circumstances.

258. The conduct of Manufacturer Defendants has fallen below the reasonable standard of care. Their negligent acts have included the following:

a. marketing opioids with misleading statements resulting in oversupply on and around the Nation of highly addictive prescription opioids;

b. enhancing the risk of harm from prescription opioids by marketing those drugs with misleading statements and omissions;

c. inviting criminal activity into the Nation by marketing opioids in violation of applicable laws and regulations;

d. failing to adhere to all applicable laws and regulations pertaining to the marketing of prescription opioids;

e. failing to train or investigate their employees properly; and

f. failing to provide adequate safeguards against misleading marketing.

259. Each Manufacturer Defendant had a responsibility to exercise reasonable care in marketing prescription opioids.

260. Each Manufacturer Defendant marketed opioids using misleading statements and omissions knowing that (a) there was a substantial likelihood this marketing would lead to sales for illicit or non-medical purposes, and (b) opioids are inherently dangerous when used for chronic pain and non-medical purposes.

261. Manufacturer Defendants were negligent or reckless in not acquiring or not utilizing special knowledge and special skills that relate to the dangerous activity of selling opioids in order to prevent or ameliorate such distinctive and significant dangers.

262. Each Manufacturer Defendant breached its duty to exercise the degree of care commensurate with the dangers involved in marketing and introducing into commerce dangerous controlled substances.

263. Manufacturer Defendants were also negligent or reckless in voluntarily undertaking duties to the Nation that they breached. Manufacturer Defendants, through their affirmative statements regarding protecting consumers, undertook duties to take all reasonable precautions to avoid misleading marketing statements.

264. Manufacturer Defendants' conduct was the cause-in-fact and proximate cause of injuries and damages to the Nation, including but not limited to the following: increased costs for the healthcare, criminal justice, social services, welfare, and education systems, as well as the cost of lost productivity and lower tax revenues.

265. The Nation is without fault, and its injuries would not have happened had Manufacturer Defendants used due care.

266. The reckless, wanton, and reprehensible nature of Manufacturer Defendants' conduct entitles the Nation to an award of punitive damages and attorneys' fees and costs.

COUNT IV
UNJUST ENRICHMENT
(Against Manufacturer Defendants)

267. The Nation realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

268. The Nation has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Manufacturer Defendants' misleading statements.

269. These expenditures by the Nation have added to Manufacturer Defendants' wealth and have helped sustain Manufacturer Defendants' businesses.

270. In this way, the Nation has conferred a benefit upon Manufacturer Defendants, by paying for what may be called their externalities—the costs of the harm caused by their misleading statements and omissions.

271. Manufacturer Defendants made substantial profits while fueling the prescription opioid epidemic in the Nation. Manufacturer Defendants continue to receive considerable profits from the sale of controlled substances in the Nation. Manufacturer Defendants are aware of these obvious benefits, and retention of these benefits is unjust. Manufacturer Defendants have been unjustly enriched by these benefits. It would be inequitable to allow Manufacturer Defendants to retain these benefits.

COUNT V
NUISANCE
(Against Distributor Defendants and Pharmacy Defendants)

272. The Nation realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

273. Distributor Defendants and Pharmacy Defendants have caused, are causing, and will continue to cause a public nuisance, in that they have committed offenses against the public order and economy of the Nation by unlawfully:

a. facilitating the diversion of prescription opioids by selling, distributing, or dispensing, or facilitating the sale, distribution, or dispensing of, such drugs from premises on and around the Nation to unauthorized users—including children, people at risk of overdose or suicide, and criminals;

b. failing to implement effective controls to guard against theft, diversion, and misuse of controlled substances from legal supply chains;

c. failing to design and operate an adequate system to detect, halt, and report suspicious orders of controlled substances; and

d. using property for repeated unlawful sales of controlled substances.

274. Defendants' activities have unreasonably interfered, are interfering, and will interfere with the common rights of the public:

a. to be free from reasonable apprehension of danger to person and property;

b. to be free from the spread of disease within the community, including the disease of addiction and other diseases associated with widespread illegal opioid use;

c. to be free from the negative health and safety effects of widespread illegal drug sales on premises on and around the Nation;

d. to be free from blights on the community created by areas of illegal drug use and opioid sales;

e. to live or work in a community in which local businesses do not profit from using their premises to sell products that serve the criminal element and foster a secondary market of illegal transactions; and

f. to live or work in a community in which community members are not under the influence of narcotics unless they have a legitimate medical need to use them.

275. Distributor Defendants' and Pharmacy Defendants' interference with these public rights has been, is, and will continue to be unreasonable and objectionable because it:

a. has harmed and will continue to harm the public health and public peace of the Nation;

b. has harmed and will continue to harm the Nation neighborhoods and communities by increasing levels of crime and thereby interfering with the rights of the community at large;

c. is proscribed by Federal laws and regulations;

d. is of a continuing nature, and has produced long-lasting effects; and

e. is known to Distributor and Pharmacy Defendants that their conduct has a significant effect upon the public rights of the Nation and its citizens.

276. In addition and independently, the Distributor Defendants' and Pharmacy Defendants' conduct invades a legally protected interest. Distributor Defendants' and Pharmacy Defendants' conduct constitutes an unreasonable, intentional, and substantial interference because, *inter alia*, each Distributor Defendant and Pharmacy Defendant has permitted dangerous drugs under their control to be diverted for illicit purposes such as to injure the Nation and its citizens.

277. Because Distributor Defendants and Pharmacy Defendants have marketed and sold prescription opioids in a manner contrary to law and because Distributor Defendants' and Pharmacy Defendants' conduct has unreasonably, intentionally, and substantially interfered with a right common to the general public, Distributor Defendants and Pharmacy Defendants are liable for public nuisance.

278. The nuisance has affected the Muscogee community in that it has undermined, is undermining, and will continue to undermine the Nation citizens' public health, quality of life, and safety. It has resulted in increased crime and property damage within the Nation. It has resulted in high rates of addiction, overdoses, and dysfunction within the Nation.

279. Public resources have been, are, and will continue to be consumed in efforts to address the opioid epidemic, thereby eliminating available resources which could be used to benefit the Nation public at large.

280. At all times, Distributor Defendants and Pharmacy Defendants had the obligation and the ability to control the sale, distribution, or dispensing of prescription opioids in the Nation. Distributor Defendants had the power to shut off the supply of illicit opioids into the Nation, and Pharmacy Defendants had the power to prevent the sale of prescription opioids in the Nation for non-medical purposes.

281. The Defendants' actions and omissions annoy, injure and endanger the comfort, repose, health and safety of the Nation, offend decency, and render the citizens of the Nation insecure in their lives and the use of property.

282. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever.

There is no legitimately-recognized societal interest in failing to identify, halt, and report suspicious opioid transactions.

283. At all times, all Defendants possessed the right and ability to control the nuisance-causing outflow of opioids from pharmacy locations or other points of sale into the surrounding Nation. Distributor Defendants had the power to shut off the supply of illicit opioids into the Nation.

284. As a direct and proximate result of the nuisance, the Nation citizens have been injured in their ability to enjoy rights common to the general public.

285. As a direct and proximate result of the nuisance, the Nation has sustained economic harm by spending substantial sums trying to fix the societal harms caused by Defendants' nuisance-causing activity, including costs to the healthcare, criminal justice, social services, welfare, and education systems.

COUNT VI
NEGLIGENCE
(Against Distributor Defendants and Pharmacy Defendants)

286. The Nation realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

287. Distributor Defendants and Pharmacy Defendants owe a duty to act reasonably under the circumstances.

288. The conduct of Distributor Defendants and Pharmacy Defendants fell below the reasonable standard of care. Their negligent acts include the following:

a. oversupplying the market on and around the Nation with highly-addictive prescription opioids;

b. using unsafe distribution and dispensing practices;

c. enhancing the risk of harm from prescription opioids by failing to act as a last line of defense against diversion;

d. inviting criminal activity into the Nation by disregarding precautionary measures built into applicable laws and regulations;

e. failing to adhere to all applicable laws and regulations pertaining to the distribution and sale of prescription opioids;

f. failing to train or investigate their employees properly;

g. failing to review prescription orders for red flags;

h. failing to report suspicious orders or refuse to fill them;

i. failing to provide effective controls and procedures to guard against theft and diversion of controlled substances; and

j. failing to police the integrity of the supply chain for prescription opioids.

289. Each Distributor Defendant and Pharmacy Defendant had a responsibility to control the sale, distribution, or dispensing of prescription opioids.

290. Each Distributor Defendant and Pharmacy Defendant sold prescription opioids when it knew or should have known that: (a) there was a substantial likelihood that many of the sales were for non-medical purposes; and (b) opioids are inherently dangerous when used for non-medical purposes.

291. Distributor Defendants and Pharmacy Defendants were negligent or reckless in not acquiring or not utilizing special knowledge and special skills that relate to the dangerous activity of selling opioids in order to prevent or ameliorate such distinctive and significant dangers.

292. Distributor Defendants and Pharmacy Defendants were also negligent or reckless in failing to guard against foreseeable third-party negligence or misconduct, including that of negligent or corrupt prescribers, pharmacists, and staff, and criminals who buy and sell opioids for non-medical purposes.

293. Each Distributor Defendant and Pharmacy Defendant breached its duty to exercise the degree of care commensurate with the dangers involved in selling dangerous controlled substances.

294. Distributor Defendants and Pharmacy Defendants were also negligent or reckless in voluntarily undertaking duties to the Nation that they breached. Distributor Defendants and Pharmacy Defendants, through their statements to the media, regulators, insurance companies, customers, and the public at large, undertook duties to take all reasonable precautions to prevent drug diversion.

295. Distributor Defendants' and Pharmacy Defendants' conduct was the cause-in-fact and proximate cause of injuries and damages to the Nation, including but not limited to the following: increased costs for the healthcare, criminal justice, social services, welfare, and education systems, as well as the cost of lost productivity and lower tax revenues.

296. The Nation is without fault, and the injuries to it would not have happened in the ordinary course of events if Distributor Defendants and Pharmacy Defendants had used due care commensurate to the dangers involved in the distribution and dispensing of controlled substances.

297. The reckless, wanton, and reprehensible nature of Distributor Defendants' and Pharmacy Defendants' conduct entitles the Nation to an award of punitive damages and attorneys' fees and costs.

COUNT VII
UNJUST ENRICHMENT
(Against Distributor Defendants and Pharmacy Defendants)

298. The Nation realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

299. The Nation has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Distributor Defendants' and Pharmacy Defendants' conduct.

300. The Nation's expenditures in providing healthcare services to people who use opioids have added to Distributor Defendants' and Pharmacy Defendants' wealth. The expenditures by the Nation have helped sustain Distributor Defendants' and Pharmacy Defendants' businesses.

301. In this way, the Nation has conferred a benefit upon Distributor Defendants and Pharmacy Defendants, by paying for what may be called Distributor Defendants' and Pharmacy Defendants' externalities—the costs of the harm caused by Distributor Defendants' and Pharmacy Defendants' improper sales, distribution, and dispensing practices.

302. Distributor Defendants and Pharmacy Defendants made substantial profits while fueling the prescription opioid epidemic in the Nation.

303. Distributor Defendants and Pharmacy Defendants continue to receive considerable profits from the sale, distribution, and dispensing of controlled substances in the Nation. Distributor Defendants and Pharmacy Defendants are aware of these obvious benefits, and that retention of these benefits is not justified under these circumstances. Distributor Defendants and Pharmacy Defendants have been unjustly enriched by these benefits. It would be inequitable to allow Distributor Defendants and Pharmacy Defendants to retain these benefits.

COUNT VIII
CIVIL CONSPIRACY
(Against All Defendants)

304. The Nation realleges and incorporates by reference the foregoing allegations as if set forth at length herein.

305. Manufacturer Defendants have engaged, and continue to engage, in a massive marketing campaign to misstate and conceal the risks of treating chronic pain with opioids. Their aggressive marketing campaign enabled Manufacturer Defendants to overcome the longstanding medical consensus that opioids were unsafe for the treatment of chronic pain and resulted in a significant increase in the number of opioids prescribed nationwide.

306. In response to and in conjunction with this increased demand, Distributor Defendants continuously supplied prescription opioids to Pharmacy Defendants, which then dispensed these prescription opioids. These transactions occurred despite Distributor Defendants and Pharmacy Defendants having actual or constructive knowledge that they were habitually breaching their common law duties and violating the FCSA.

307. Without Manufacturer Defendants' misrepresentations, which created demand, Distributor Defendants would not have been able to sell to Pharmacy Defendants the increasing number of orders of prescription opioids for non-medical purposes throughout the Nation.

308. Without Distributor Defendants' supply of prescription opioids, Pharmacy Defendants would not have been able to fill the increasing number of orders of prescription opioids for non-medical purposes throughout the Nation.

309. None of the Defendants would have succeeded in profiting so much from the opioid epidemic without the concerted conduct of the other parties.

310. The Defendants agreed with each other to accomplish the unlawful purposes of marketing, selling, distributing, and retailing prescription opioids through violations of law and misrepresentations. The Defendants performed numerous overt acts in furtherance of this conspiracy, including marketing, selling, distributing, and retailing prescription opioids by means of misrepresentations and omissions, violating Federal and state laws, and turning a blind eye to diversion of prescription opioids.

311. As a result of the concerted action between Manufacturer Defendants, Distributor Defendants, and Pharmacy Defendants, the Nation and its citizens have suffered damages.

312. Defendants are jointly and severally liable for the results of their concerted efforts.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, the Nation, prays that this Court enter judgment in its favor against Defendants and:

a. On Count I (Lanham Act Violation Against All Defendants):

i. Enter an order awarding the Nation its actual damages stemming from Defendants' violations of the Lanham Act; and

ii. Award the Nation the costs of bringing this action, investigative costs and fees, attorneys' fees, and such other and additional relief as the Court may determine to be just and proper.

b. On Count II (Nuisance Against Manufacturer Defendants):

i. Order Manufacturer Defendants to pay the expenses the Nation has incurred or will incur in the future to abate fully the nuisance they have caused;

ii. Award the Nation punitive damages; and

iii. Order such further relief as justice and equity may require.

c. On Count III (Negligence Against Manufacturer Defendants):

i. Award the Nation compensatory damages for the increased costs to the Nation healthcare, criminal justice, social services, welfare, and education systems, as well as the cost of lost productivity due to Manufacturer Defendants' negligence;

ii. Award the Nation punitive damages;

iii. Award the Nation attorneys' fees and costs; and

iv. Order such further relief as justice and equity may require.

d. On Count IV (Unjust Enrichment Against Manufacturer Defendants):

i. Award the Nation restitution of its costs caused by Manufacturer Defendants' actions, including the costs of addressing Defendants' externalities and the costs of prescription opioids paid for by the Nation;

ii. Disgorge Manufacturer Defendants of all amounts they have unjustly obtained; and

iii. Order such further relief as justice and equity may require.

e. On Count V (Nuisance Against Distributor Defendants and Pharmacy Defendants):

i. Order Distributor Defendants and Pharmacy Defendants to pay the expenses the Nation has incurred or will incur in the future to abate fully the nuisance they have caused;

ii. Award the Nation punitive damages; and

iii. Order such further relief as justice and equity may require.

f. On Count VI (Negligence Against Distributor Defendants and Pharmacy Defendants):

i. Award the Nation compensatory damages for the increased costs to the Nation's healthcare, criminal justice system, social services, welfare, and education systems, as well as the cost of lost productivity due to Distributor Defendants' and Pharmacy Defendants' negligence;

ii. Award the Nation punitive damages;

iii. Award the Nation attorneys' fees and costs; and

iv. Order such further relief as justice and equity may require.

g. On Count VII (Unjust Enrichment Against Distributor Defendants and Pharmacy Defendants):

i. Award the Nation restitution of its costs caused by Distributor Defendants' and Pharmacy Defendants' actions, including the costs of addressing Distributor Defendants' and Pharmacy Defendants' externalities and the costs of prescription opioids paid for by the Nation;

ii. Disgorge Distributor Defendants and Pharmacy Defendants of all amounts they have unjustly obtained; and

iii. Order such further relief as justice and equity may require.

h. On Count VIII (Civil Conspiracy Against All Defendants):

i. Award the Nation compensatory and punitive damages for the conspiracy in which Manufacturer Defendants, Distributor Defendants, and Pharmacy Defendants engaged; and

ii. Order such further relief as justice and equity may require.

REQUEST FOR JURY TRIAL

The Nation respectfully requests that all issues presented by its above Complaint be tried by a jury, with the exception of those issues that, by law, must be tried before the Court.

Date: April 3, 2018

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